

Collaborative Opportunities for Multidisciplinary, Bold, and Innovative Neuroscience (COMBINE) (RM1, RFA-NS-23-027)

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- Review: Bo-Shiun Chen and Li Jia
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For more information, visit <u>https://www.ninds.nih.gov/funding/about-funding/ninds-grant-mechanisms/RM1-team-science</u> You can also email your NINDS Program Official or <u>NINDSTeamScience@nih.gov</u>.

Navigating the COMBINE (RM1) Program, RFA-NS-23-027

- 1. Why team science?
- 2. NINDS COMBINE Program (<u>Section I</u> of the FOA)
 - Key features; What is new with COMBINE?
 - Is this a good fit for your collaboration?
- 3. Application (<u>Section IV</u>)
- 4. Review Criteria (<u>Section V</u>)
- 5. Next Steps
- 6. Q&A- enter your questions in chat

"Stronger together through interdisciplinary team science"

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

3



NINDS COMBINE Interdisciplinary opportunities

• A goal that challenges existing paradigms, overcomes long-standing roadblocks to progress, and/or develops new synergies across different scientific fields

- Basic, translational, and/or clinical collaborations with a goal of reaching a significantly higher mechanistic understanding of nervous system function and/or dysfunction
- Challenges in understanding and targeting disease modifying therapies that require collaborations across basic, translational, and/or clinical disciplines
- Scientific efforts requiring integration of previously siloed and/or disparate areas of scientific or technical expertise
- Challenges that necessitate bridging across species, scales and disciplines (e.g., to reveal shared/generalizable and/or unique neural processes)
- A scientific question that requires leveraging an innovative combination of tools and approaches, or the application of cutting-edge tools, resources, conceptual, or computational frameworks (*such as those arising from the BRAIN initiative*)



Navigating the COMBINE (RM1) Program, RFA-NS-23027

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Key Features of the NINDS COMBINE program (What is new? - highlighted in yellow)

- Transformative 5-year goal fully within NINDS mission
 - Bold, impactful, and challenging
 - Single, focused goal that can only be achieved through interdisciplinary team science (Multiple aims are non-responsive)
- 3-6 MPIs integrating distinct viewpoint/expertise (at least 2.4 cal mo effort each, subject to <u>SCR policy</u>)
- Sufficient scope and complexity to warrant a team approach (as opposed to MPI R01); ~\$500K - \$1.5M DC
- Thoughtful plans for team management and enhancing diverse perspectives

6 Collaborative Opportunities for Multidisciplinary, Bold, and Innovative Neuroscience (COMBINE) (RM1, <u>RFA-NS-23-027</u>) Application receipt dates: October 20, 2023 and October 8, 2024.

PI Expertise #1 PI Expertise #2 PI Expertise #3





NINDS COMBINE (RM1) Program, RFA-NS-23-027: What are we looking for?



- Bold and impactful
 - Transformative objective with defined 5-year outcomes
 - A goal that challenges existing paradigms, overcomes long-standing roadblocks to progress, and/or develops new synergies between different scientific fields
- Challenging
 - Can only be achieved through a team-based approach ("Why is the team approach needed to address the scientific issue at hand?")
- Applications will *assume some degree of risk* and are in general more ambitious and innovative than traditional NIH applications. Because feasibility will be assessed, applicants should carefully manage any risk in the premise and/or approach.





Goal

Scale

Approach

NINDS COMBINE (RM1) Program, RFA-NS-23-027: What are we looking for in the MPIs?





- Innovative combination of distinct fields/expertise from 3-6 MPIs to pursue a single goal or problem
- Essential contributions from each of the 3-6 MPIs (as reflected in aims, effort, and plans for leadership and management)
 - Bandwidth: 2.4 Cal months; subject to SCR policy
 - Teams must not be dominated by a single individual
 - Combined/integrated efforts- Not a collection of individual efforts or interrelated and parallel projects



NINDS COMBINE (RM1) Program, RFA-NS-23-027: What are we looking for in the structure?





For a truly **integrated** collaborative project:

- 1. *New* Pursuing 1 single focused goal (multiple aims are non-responsive)
 - This feature distinguishes the COMBINE program from R01 and P01.
- 2. All contributions and pieces are essential to the goal.
 - Deletion test- if you remove a piece, the goal falls apart
- 3. Substantial and integrated contributions across the PD/PIs. Not a collection of individual or series of efforts, or interrelated and parallel projects.
 - Will a series or several separate R01s, or a multi-component P01 be a better fit? Why do these pieces needed to be studied together?
- 4. Intentional about **integrating** efforts: Includes activities, planned outcomes, approaches, experiments, modeling, and/or frameworks that act as **"glues"**, serving to integrate and combine efforts across disciplines and team members.
 - What is unifying all these pieces together that is necessary to achieve the specified goal?



NINDS COMBINE (RM1) Program, RFA-NS-23-027: What are we looking for in terms of scale?





- Shared leadership across 3-6 MPIs, each with a distinct scientific viewpoint or expertise necessary to pursue the interdisciplinary approach
- Scale will likely benefit from resources for team management (e.g., Program manager, data scientist; these resources can be requested under the "Team Management Plan" and included in budget)
- Scale will benefit from expanded page limit for Research Strategy (15-page max) and defined Team Management Plan, Timeline and Benchmarks for Success, and Plan for Enhancing Diverse Perspectives (Other attachments)



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Ideal COMBINE Program





3-6 MPIs integrating and combining distinct expertise necessary to solve a single, focused, transformative goal within
5-years

Thoughtful plan for managing the team and feasibility and for incorporating diverse perspectives



What characteristics/features will not be a good fit?





- Not well-integrated
- A collection of individual, parallel, or series of efforts (Better off as a P01 or multiple/series of R01s)
- Plan is not cohesive; multiple aims (nonresponsive) instead of a single, focused goal
- Some pieces are not essential to the goal, or not necessary to study altogether. (minimal impact to the project if deleted)

- A dominant PI plus supporting roles from the other PIs
- Does not have 3-6 MPIs with distinct expertise and viewpoint

- Overly broad; open-ended types of projects
- Goal is not well-defined or has a low likelihood of being completed within 5 years



What topics will not be a good fit? (Section I)

- Research that is not fully within the NINDS mission
- Better fit for other Institutes and/or specific funding opportunities
 - e.g., Better fit for other programs (BRAIN, HEAL, etc)- "The COMBINE RM1 has fixed and limited budget commitments, so funding priorities will include considerations where the research might better fit special funding programs like the NIH BRAIN initiative, HEAL Initiative, ADRD, and other active programs."
- > Applications in which the primary goal is to create, maintain, expand, and/or disseminate resources or infrastructure

Considerations about translational and clinical types of applications:

- Applications that propose to discover and develop a small molecule, biologic therapeutic, or therapeutic device to treat neurological and/or neuromuscular disorders (covered by <u>NINDS Division of Translational Research Programs</u>).
- Development and validation of biomarkers for use in clinical trials or in clinical practice. These types of applications are already covered by the NINDS Biomarker Program funding opportunities (PAR-22-089 and PARs-21-056, 057, 058, and 059), see: <u>NINDS: Focus On Biomarkers Research.</u>
- Clinical trials designed to answer specific questions about safety, tolerability, efficacy and/or effectiveness of pharmacologic, behavioral, biologic, surgical, or device (invasive or non-invasive) interventions (e.g., phase I, phase II, phase III, or pivotal clinical trials). Such designs should be submitted to an NINDS clinical trial-specific funding announcement (see <u>NINDS: Clinical Research</u>). If planning a clinical trial, **this NOFO will only accept mechanistic or BESH (Basic Experimental Studies Involving Humans) types of clinical trials.** Understanding the distinction between mechanistic, BESH, and efficacy trials can be difficult. PIs are strongly encouraged to discuss any planned clinical trial in consideration for this opportunity with the scientific program contact to avoid errors in interpretation.
- Clinical research projects with an inherently team science approach (e.g., applications in which the primary goal is multi-site clinical epidemiological or observational studies, genetic studies, or comparative effectiveness research). NINDS will continue to consider these large projects as a separate, unsolicited independent investigator-initiated projects (i.e., R01/U01 applications). For comparative effectiveness research projects, see: <u>PAR-22-076</u>: <u>Prospective Observational Comparative Effectiveness Research in Clinical Neurosciences</u> (UG3/UH3 Clinical Trial Not Allowed).

Non-responsive applications will not proceed to review and will be withdrawn. Please consult us!

Comparison of NINDS Team Science mechanisms

R01 Parent

P01 Program Project



- Multiple Projects+Cores
- *Team-specific* features and resources
- Single Special Emphasis Panel



- Multiple Aims
- Not team-specific
- Multiple study sections

3-6 MPIs 1 Goal

RM1 COMBINE

- 1 goal/multiple aims are nonresponsive
- *Team-specific* features and resources
- Single Special Emphasis Panel
- Larger scale, more complex than R01



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Preparing the RM1 application

- 1 receipt date per year: October 20, 2023 and October 8, 2024
- 1 goal for the whole RM1 project + 15-page Research Strategy + 3 "Other Attachments"
 - 1. Team Management Plan (3-page max),
 - 2. Timeline and Benchmarks for Success (2page max)
 - 3. Plan for Enhancing Diverse Perspectives (1page max, "PEDP")





Described fully in RFA <u>Section IV</u>

Application Structure is different from typical NIH applications



TRANSFORMATIVE. INTEGRATED. INNOVATIVE

- Address "how will the project challenge existing paradigms, overcome long-standing roadblocks to progress, and/or develop new synergies across different scientific fields?"
- Be intentional about **integrating** efforts: Highlight activities, planned outcomes, approaches, experiments, and/or frameworks that act as "glues", serving to integrate and combine efforts across disciplines and team members.
- Applications will assume some degree of risk and are in general more ambitious and innovative than traditional NIH applications. Because feasibility will be assessed, applicants should carefully manage any risk in the premise and/or approach.

Specific Aims and 15-page Research Strategy: structured differently (see <u>Section IV</u>).

- Specific Aims Page: Multiple aims are inappropriate as the research plan must be focused on pursuing a single focused goal.
- Research strategy (15-page max). Use subheadings: "Importance of the Research and Appropriateness for the NINDS COMBINE program" and "Approach and Experimental Design".

- **3 Other Attachments:** The success of team science hinges on
 - Well-managed team interactions (Team Management Plan is complementary to MPI Leadership Plan).
 - Clear Timelines and Benchmarks for Success
 - Evidence of commitment to diversity, equity, and inclusion (Plan for Enhancing Diverse Perspectives (PEDP))
 - Definition of "diverse perspectives" is broad
 - Unique and customized to the proposal; Summary of strategies+ timeline/milestones+approach to assess progress



Application Structure is different from typical NIH applications



TRANSFORMATIVE. INTEGRATED. INNOVATIVE

- Address "how will the project challenge existing paradigms, overcome long-standing roadblocks to progress, and/or develop new synergies between different scientific fields?"
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Preparing the RM1 application: Science



Described fully in RFA Section IV

Specific Aims Page:

- Single 5-year scientific goal or aim (Multiple aims are inappropriate)
- Team structure and fit with COMBINE program
- Schematic of the overall strategy, approach, and experimental design that will enable achievement of the single goal within 5-years.
- Integration overview: Highlight activities, planned outcomes, approaches, experiments, and/or frameworks that will integrate and combine efforts across disciplines and team members.

Research Strategy (15-page max):

- Defined subheadings
 - I. Importance of the Research and Appropriateness for the COMBINE program
 - A. Importance of the Research
 - B. Appropriateness for the COMBINE program
 - II. Approach and experimental design



Application Structure is different from typical NIH applications



TRANSFORMATIVE. INTEGRATED. INNOVATIVE

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Other Attachment #1: Team Management Plan (3-page max)

- > The success of team science hinges on effective leadership, management, and coordination.
- Whereas the "Multiple PD/PI Leadership Plan" focuses on leadership by and interactions across the PD/PIs, the "Team Management Plan" focuses on management of the whole team/key personnel.
- Applicants are encouraged to consult resources to aid in developing effective team-based programs (see e.g., the <u>NCI Collaboration and Team Science Field Guide</u>)
- No sample template, but we recommend that PIs structure the plan with these subheadings (detailed in <u>FOA</u> <u>section IV</u>):
 - Organizational structure and team composition (can include here justification for a program manager/coordinator)
 - Shared vision, contributions, and distributed responsibility for decision making
 - Resource sharing and allocation across the team
 - Credit Assignment (*must take into account how credit will be shared especially with trainees and other early career stage investigators*)
 - Knowledge transfer across disciplines and career stages
 - Coordination and communication plans (should be inclusive of all relevant personnel)
 - Intra-team data sharing, archiving, and preservation (this focuses on intra-team data processes, which is different from the data sharing plan that focuses on sharing data to the public)

Other Attachment #2: Timeline and Benchmarks for Success (2-page max)

- For reviewers to be able to assess feasibility and the degree of integration and collaboration.
- Includes a project timeline (Gantt chart/table (or similar)) that includes all major tasks to be performed during the project as well as critical benchmarks for success
 - Chart includes estimated start and completion dates for those tasks and should identify the contributions expected from each PD/PI toward accomplishing each task. [For a truly integrated collaborative project, highlight specific activities and/or planned outcomes that act as **"glues"**, serving to combine and integrate efforts across disciplines and team members.]
- Assessed under "Approach" in the review criteria



Other Attachment #3: Plan for Enhancing Diverse Perspectives (1-page max) "PEDP"

What is a PEDP? A summary of strategies to advance the scientific and technical merit of the proposed project through inclusivity.

- To capitalize on innovative ideas, distinct perspectives, variety of experiences, training, backgrounds, and skillsets
- Definition of "diverse perspectives" is broad

WHO DO the research

Investigators/trainees who are:

- historically underrepresented in the biomedical research workforce (<u>NOT-</u> <u>OD-20-031</u>)
- from different scientific disciplines
- at varying career stages
- with varied skills, experience, and expertise

WHO PARTICIPATE in the research

- Recruit diverse participants for human studies.
- Use of specimens derived from varied ancestries.
- Any projects involving human participants or samples derived from humans should be collected in an ethically sound manner and consented appropriately

WHERE research is done

 Participation of researchers from diverse organizations and institutions (e.g., research intensive & active, undergraduate, minorityserving, community-based, etc.).

Other Attachment #3: Plan for Enhancing Diverse Perspectives (1-page max) "PEDP"



** Each PEDP will be unique and will depend on the content and structure of the scientific aims, the required expertise, the environment, and the performance site(s). **

- Examples of potential strategies
 - Inclusion of personnel with diverse perspectives
 - > Training, mentoring, and/or recruitment of diverse groups
 - Publication plans with equitable authorship policies
 - > Outreach activities (diverse groups, public stakeholders, etc)
 - Full instructions including FAQs and examples: <u>https://www.ninds.nih.gov/funding/about-funding/ninds-grant-mechanisms/ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-team-science-grant-rm1-clinical-trial-optional/pedp-ninds-interdisciplinary-t</u>

Assessed in every component of the review criteria



Budget



> Budget limits:

- Application budgets need to reflect the actual needs of the proposed project. (typically ~\$500,000-\$1.5M direct costs.)
- \$10M total first year costs (per fiscal year) to fund 4-6 awards.
- Other allowable costs?
 - PEDP implementation costs
 - Data sharing costs (across labs and to the public); please note requirements specified in the new NIH Data Management Sharing Policy and the COMBINE Team Management Plan
 - Personnel and/or software for team management (e.g. program manager, data science staff)
- Other things to note:
 - No escalation on any categories, (including salary cost of living increases)
 - Make sure the budget sheets match the budget justification



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Review Criteria (Specific to this FOA)



Criterion	Location in Application	Important Points
Significance	Specific Aims Page, Research Strategy	If successful, to what extent will the proposed program's integrated team research effort be transformative and uniquely advance a scientific area? To what extent does the goal challenge existing paradigms, overcome long-standing roadblocks to progress, and/or develop new synergies between different scientific fields? Is the program of sufficient scope and complexity to warrant a team approach? Does the single scientific goal require an integrated interdisciplinary effort? Can definitive outcomes be accomplished during the 5-year funding period?
Investigators	Biosketches, Team Management Plan, MPI Leadership Plan, Research Strategy, Research Support	Is the planned effort by the PDs/PIs complementary, appropriate, and sufficient for the work proposed? Is the diversity of investigator backgrounds and expertise sufficient to address the proposed scientific problem? Is it clear that each investigator is necessary and will contribute to achieving the goals of the program? Teams must not be dominated by a single individual. Is there evidence for synergistic interactions among PDs/PIs beyond the additive benefits of additional investigators? If the application includes collaborating investigators who will not receive direct support, is it clear how these investigators will participate in the program? If foreign investigators are involved, are they uniquely qualified to participate in the team? Team Management Plan (Attachment): Does the team management plan instill confidence that fair and adequate governance processes will be used for decision-making, conflict resolution, and resource allocation? Does the plan ensure that all investigators will have a voice in decision-making and that no single PD/PI will become overly dominant? Does it provide for effective team leadership and management with shared responsibility and decision-making processes? Is the team plan sufficiently detailed to create a sustainable environment for maintaining integration, productivity, and shared vision? Does the management plan include adequate plans for shared professional credit? Does the management plan include adequate plans for knowledge transfer? To what extent will trainees be involved in and benefit from this team science? If shared research resources will be utilized, are plans adequate? If a scientific program manager or coordinator is proposed, are the qualifications and role of this individual appropriate? Are adequate plans presented to establish and sustain a team of researchers with an optimal range of backgrounds, expertise and skills, and plans to arrive at major decisions, accounting for different points of view? Are adequate plans presented to manage intrate



RM1 Review Criteria (Specific to this FOA)



Criterion	Location in Application	Important Points
Innovation	Specific Aims Page, Research Strategy	Does the program involve innovative ideas or approaches that would be very difficult to pursue through independently funded individual or multiple PD/PI research project grants? Does the program involve innovative combinations of scientific fields and/or intellectual viewpoints to address its goals? Is innovation evident in the method that the established areas of science are combined?
Approach	Specific Aims Page, Research Strategy, Timeline/Benchmarks for Success	Is the program presented as a single, focused scientific goal instead of multiple aims? Does the combination of scientific expertise (represented by the PD/PIs) present a compelling case that collaborative, interdisciplinary research will enable scientific advance? To what extent will the strategy, planned outcomes, and activities designed to integrate and combine efforts across fields and team members? Are all contributions by each team member and pieces of the experimental plan synergistic, integrated, and essential to the goal? Does the work plan make adequate use of existing institutional and/or regional resources? If new resources or equipment are requested, are they well justified and not redundant with resources available elsewhere in the institution or region? Although feasibility is considered, unavoidable risks that are intrinsic to new and innovative approaches should not be penalized. Evaluate methodological rigor and rationale for the design and components. Timeline and Benchmarks for Success (Attachment) : Are the timeline and benchmarks proposed appropriate for accomplishing the single scientific goal? Is there sufficient detail on the timing and duration of key project tasks? Are the timelines proposed for achieving project goals realistic and inclusive of necessary steps, but also efficient without adding unnecessary steps? Do the contributions from the PD/PIs suggest a high degree of commitment, integration, and collaboration ?
Environment	Research Strategy, Facilities/Equipment, Letters of Support	Are the resources and infrastructure adequate for accomplishing the single scientific goal and supporting team science? Is there synergy to be gained from the involvement of multiple departments and/or institutions? Will the range of departments and/or institutions involved enhance the diversification of the team in terms of the backgrounds, and expertise and skills of the researchers? If foreign organizations are involved, do they provide unique resources that are not otherwise available?



PEDP Review Criteria



Criterion	Important Points
Significance	To what extent do the efforts described in the Plan for Enhancing Diverse Perspectives further the significance of the project
Investigators	To what extent will the efforts described in the Plan for Enhancing Diverse Perspectives strengthen and enhance the expertise required for the project?
Innovation	To what extent will the efforts described in the Plan for Enhancing Diverse Perspectives meaningfully contribute to innovation?
Approach	Are the timeline and milestones associated with the Plan for Enhancing Diverse Perspectives well-developed and feasible?
Environment	Is there synergy to be gained from the involvement of multiple departments and institutions?

- Reveiwers will be asked to weigh strengths and weaknesses will be associated with each of the review criteria
- The PEDP evaluation will contribute to the criterion scores and overall impact score of each application. It is expected that a PEDP judged by reviewers as insufficient, can negatively impact criterion score(s) and overall impact score.



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Next steps



Application receipt dates: October 20, 2023 and October 8, 2024.

Only COMBINE RM1 applications that are fully within the <u>NINDS mission</u> will be accepted and considered for funding by <u>NINDS</u>. To determine if your proposal fits the NINDS mission and RM1 mechanism, please provide the following information in a <u>one-page word/PDF</u> to your <u>NINDS Program Official</u> or to NINDSTeamScience@nih.gov as soon as possible:

<u>Title</u>

<u>Team Composition</u> (Names, Title, Affiliation, 1-3 expertise keywords) <u>Planned Goal</u> (Describe the single focused goal and its transformative nature) <u>Approach</u> (Briefly describe the research strategy and the need for an interdisciplinary and integrated approach) <u>Budget</u> (Estimated total costs with broad categorizations (personnel, equipment, travel, F&A, etc.))

Note: The COMBINE RM1 has fixed and limited budget commitments, so funding priorities will include considerations where the research might better fit special funding programs like the <u>NIH BRAIN initiative</u>, <u>HEAL Initiative</u>, <u>AD/ADRD</u>, and other active programs.





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Q&A Session



- Q&A
 - FAQs
 - Questions from the live audience
- Unaddressed questions- Please see our website FAQs or email <u>NINDSTeamScience@nih.gov</u>



FAQs (Review)



> Is there a preference for new or established collaborations?

No- this program supports highly integrated teams that are either new collaborators or established teams of investigators. For newly established collaborations, it is imperative to include approaches to ensure successful team communication and collaboration.

> What, if any, preliminary data are required?

Preliminary data are not required but it can strengthen the premise and feasibility. If preliminary data are not available, applicants are encouraged to present other evidence of feasibility (e.g. track record, expertise, alternative approach, and other measures that mitigate risk).

What study section reviews the COMBINE program, and how can I serve on the Team Science COMBINE study section?

A specific NINDS study section (Special Emphasis Panel) will be assembled. Reviewers will be recruited based on expertise needed for the meeting. If interested in serving on the study section, please contact Bo-Shiun Chen, <u>bo-shiun.chen@nih.gov</u>.



FAQs (Policy)



> How will the NIH Special Council Review (SCR) Policy be applied to non-percentiled applications?

-Multiple PD/PI projects will be subject to the NINDS Special Review Council policy if one or more of the PD/PIs has NIH research support exceeding the limit of the SCR policy (\$2M total costs inclusive of the pending application).

- If an MPI in the team is subject to this SCR policy, the pending application will be subjected to a more stringent payline (referred to here as the "SCR payline"). (e.g. if cut-off is a score of 30, the SCR application will have to score a 15 or better to be considered for funding.)

https://www.ninds.nih.gov/funding/determining-your-funding-likelihood/ninds-paylines/special-council-review

> How does being a PI on a COMBINE application effect Early Stage Investigator (ESI) status?

If you serve as PI on a funded COMBINE RM1 program, you will no longer be eligible for ESI. Other RM1 roles do not affect ESI status (Co-I, Consultant, etc). For more information: https://grants.nih.gov/grants/esi-status.pdf

> Can an R35 awardee serve as a PI in a COMBINE application?

No. Instead of serving as a PI, NINDS R35 awardees can participate as a collaborator of the COMBINE and may not receive additional funds from this award.



FAQs (Grants management)

> Are Intramural investigators allowed to apply?

The requests by NIH intramural scientists will be limited to the incremental costs required for participation. Should an extramural application include the collaboration with an intramural scientist, no funds for the support of the intramural scientist may be requested in the application. The intramural scientist may submit a separate request for intramural funding as described above.

> Are foreign participants allowed to apply?

(See FOA Section III: Eligibility)

Yes, foreign components, as <u>defined in the *NIH Grants Policy Statement*</u>, **are** allowed. If foreign investigators are involved, it should be described how they are uniquely qualified to participate in the team and/or how they will provide unique resources that are not otherwise available.

Is there a budget limit per project?

There is a cap for the whole program- \$10M total cost. Application budgets need to reflect the actual needs of the proposed project. (typically ~\$500,000-\$1.5M direct costs.) Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.



FAQ: How is the RM1 different from the P01 and MPI R012



NINDS <u>P01</u>	Parent R01	NINDS COMBINE Program
Synergy, collaboration, team science efforts (Parallel/interrelated efforts)	Efforts from single lab to small teams	Synergy, collaboration, team science efforts (integrated and interdisciplinary)
Interrelated projects; Multi-component (minimum of 3 research components- projects + cores)	1 set of aims; 12-page research strategy	1 goal (multiple aims not allowed) + 15-page Research Strategy + 3 "Other Attachments" (Team Management Plan (3-page max), Timeline and Benchmarks for Success (2-page max), and Plan for Enhancing Diverse Perspectives (1-page max, PEDP)
Review each component + overall ; NINDS SEP	Review 1 project; CSR	Review 1 project + Other Attachments (3); NINDS SEP
PPG director- established leader, driver of the project	Depends on the project	Emphasis on multi-PI collaboration and shared leadership across 3-6 MPIs
Coordination by an administrative core; diversity as a scorable criteria	MPI specific language	Coordination described in the team management plan; diversity as a scorable criteria; Can allot resources for a program manager/coordinator and for intra-team data management; specific review criteria
3x per year (~May, June, January)	Standard dates	Once per year: October 20, 2023 and October 8, 2024 (Max Council)
	NINDS P01Synergy, collaboration, team science efforts (Parallel/interrelated efforts)Interrelated projects; Multi-component (minimum of 3 research components- projects + cores)Review each component + overall ; NINDS SEPPPG director- established leader, driver of the projectCoordination by an administrative core; diversity as a scorable criteria3x per year (~May, June, January)	NINDS P01Parent R01Synergy, collaboration, team science efforts (Parallel/interrelated efforts)Efforts from single lab to small teamsInterrelated projects; Multi-component (minimum of 3 research components- projects + cores)1 set of aims; 12-page research strategyReview each component + overall ; NINDS SEPReview 1 project; CSR SEPPPG director- established leader, driver of the projectDepends on the projectCoordination by an administrative core; diversity as a scorable criteriaMPI specific language3x per year (~May, June, January)Standard dates

For all mechanisms, budget is not limited but needs to be commensurate to the scope. Above 500k DC needs NINDS approval for P01 and R01.

FAQs (Program)



Is my topic X within NINDS mission?

Because topics are often shared across institutes and NIH programs, we highly recommend that you check on this with us by sharing us your project summary or draft of aims.

Is this RFA for a single site ? Can it be for multisites? Are PIs expected to be from different institutions or can they all be from the same place? Can the team be made up of different disciplines within a single department? Would it be OK for form a team consisting of expertise on each step of an entire biological process? Who should be on the team?

The science should drive the type of collaboration and the team/expertise composition. Being in different vs same institution/departments could differ in logistical considerations, so this should be accounted for in the team management plan.

Is there a recommended effort for the Pis?

Programs of this level of complexity are expected to require significant effort from all PDs/PIs involved. Generally, each PD/PI should devote at least 2.4 person months (i.e., the equivalent of 20% effort on a full-year appointment, 26.7% on a 9-month appointment, or 40% on a 6-month appointment) throughout the duration of the award.





Thank you!

Collaborative Opportunities for Multidisciplinary, Bold, and Innovative Neuroscience (COMBINE) (RM1, RFA-NS-23-027)

- Program: Karen David and Cory Kelly
- Review: Bo-Shiun Chen and Li Jia
- Policy and Extramural Activities: Alisa Schaefer and Dave Owens

For more information, visit <u>https://www.ninds.nih.gov/funding/about-funding/ninds-grant-mechanisms/RM1-team-science</u> You can also email your NINDS Program Official or <u>NINDSTeamScience@nih.gov</u>.

NINDS COMBINE (RM1) Program, RFA-NS-23-027: What are we looking for in the structure?





For a truly **integrated** collaborative project:

- All contributions and pieces are essential to the goal.
 - Deletion test- if you remove a piece, the goal falls apart
- *New* Pursuing 1 single focused goal (multiple aims are non-responsive)
 - This feature distinguishes the COMBINE program from R01 and P01.
- Substantial and integrated contributions across the PD/PIs. Not a collection of individual or series of efforts, or interrelated and parallel projects.
 - Will a series or several separate R01s, or a multi-component P01 be a better fit? What is the value added/Why do these pieces needed to be studied together?
- Intentional about integrating efforts: Includes activities, planned outcomes, approaches, experiments, and/or frameworks that act as "glues", serving to integrate and combine efforts across disciplines and team members.
 - What is unifying all these pieces together that is necessary to achieve the specified goal?

