Frequently Asked Questions (FAQs) for RFA-HD-25-001: Medical Rehabilitation Research Resource (P50 Clinical Trial Optional)

General FAQs

1. **Q: Are the specific aims pages separate from the page limits for each research strategy page limit?**
   Answer**:** Yes. Each component can have a 1-page specific aims page submitted as its own attachment. The page limits in the table refer to the Research Strategy attachment. When the final application pdf is compiled, the Specific Aims attachment will immediately proceed the Research Strategy.

2. **Q: What is the expected experience of the Principal Investigator (PI) or Multiple PIs (MPIs)? Are Early Stage Investigators (ESI) and/or junior faculty encouraged to apply?**
   Answer: Investigators from all career stages are encouraged to apply. PIs and MPIs should demonstrate their qualifications to conduct the proposed work in the application. ESIs will not receive the same funding consideration that they would for an R01.

3. **Q: Are MPI applications accepted?**
   Answer: Yes.

4. **Q: Will applications in response to RFA-HD-25-001 P50 be subject to NICHD Special Council Review Procedures as described in NOT-HD-23-038?**
   Answer: NOT-HD-23-038 requires special council review when a PI currently holds NIH Research Project Grants exceeding $1M in total cost. This policy does not apply to applications to Requests for Applications, including RFA-HD-25-001. In addition, P50 grants are considered Research Resources and not Research Project Grants so P50 funding does not contribute to the $1M total cost funding that is described in NOT-HD-23-038.

5. **Q: Can an application target more than 1 of the focus areas?**
   Answer: Yes. However, the benefits of targeting additional focus areas are limited compared to addressing at least one. Attempting to address too many focus areas may make the application seem unfocused.

6. **Q: Should your proposal target a single participating Institute or Center?**
   Answer: Applications should respond to the RFA which emphasizes wide application to Rehabilitation Research.

7. **Q: Is there a limit for number of applications from an institution?**
   Answer: There is not a limit on applications, but two applications from the same institution would need to be highly meritorious and distinct for both to be considered for funding.

8. **Q: Will more than one center be funded in a priority area?**
   Answer: Two applications in the same priority area would need to be highly meritorious and distinct for both to be considered for funding.

9. **Q: Would it be appropriate to test an intervention (clinical trial) for the research project?**
   Answer: Yes, clinical trials are allowed; however, the overall purpose of the application cannot be an efficacy trial in a single condition. An application designed to test an efficacy

trial in a single condition would be non-responsive and administratively withdrawn prior to review.

10. **Q: Would you recommend developing devices rather than relying on commercially available ones?**
Answer: Both approaches would be responsive to the Request for Application (RFA). Applicants would need to justify the choice of device in the application.

11. **Q: Would leveraging current infrastructure and/or cores to support the new P50 cores or research project be acceptable?**
Answer: Yes. Applicants are encouraged to leverage existing resources, including those at applicant institutions, to support the application. However, applications to this RFA may be weakened if they are dependent on resources that may lose (or need to renew) independent funding during the P50 project period.

12. **Q: Does the center have to be standalone, or could it be part of an existing institutional center?**
Answer: Existing resources can be leveraged, but the proposed center should be distinct to allow for accounting and evaluation.

13. **Q: Will you lose ESI status as a PI of a P50?**
Answer: If an ESI is assigned a PD/PI role for the application, the individual will lose their ESI status when the award is made. If the ESI is the lead of a project or core, but not the PD/PI for the overall application, the individual will retain ESI status when the award is made.

14. **Q: Can international collaborators be included in the application?**
Answer: Foreign components are allowed. Please review the NIH Grants Policy statement for more detail. Applications from foreign institutions are not allowed.

15. **Q: Do existing centers will get preference?**
Answer: Renewal applications are not being accepted in response to this RFA. Historically, the Medical Rehabilitation Research Program has had approximately 50% turnover.

16. **Q: Is there a preference toward analyzing data that is already collected in a novel way versus collecting new data with a new tool.**
Answer: Both approaches would be responsive to the RFA. Applicants would need support the chosen approach.

Budget FAQs

1. **Q: Should the costs of the conference in the Community Outreach Core be included in that Core's budget?**
Answer: Yes.

2. **Q: For a multi-institution proposal, how should the contact institution account for subcontract indirect costs?**
Answer: RFA-HD-25-001 does not include any special provisions regarding subcontracts. Please follow standard NIH procedure from the NIH Grants Policy Statement and supporting documentation.

3. **Q: Should pilot projects be budgeted like regular subawards?**
Answer: Yes, pilot projects should be budgeted as subawards.

4. **Q: Can we use a reduced F&A rate for the Pilots rather than full rate?**

Answer: Yes, this is permitted under NIH policy.

5. **Q: If an applicant elects to fund pilot projects can the applicant request $150,000 *per year* for the Opportunity Pool?**
Answer: Yes, the applicant can request $150,000 **per year**, inclusive of all direct and indirect costs. The $150,000 per year is in addition to the $750,000 per year direct costs and associated indirect costs that may be requested with the P50 application.

Review FAQs

1. **Q: Is a single final score given that includes the scores for the Overall Section, Research Project and 3 Cores? If so, how is this calculated?**
Answer: Overall impact scores are not calculated or averaged from the component scores. Reviewers assign the overall score while considering other component scores but have the discretion to assign the overall score they deem most appropriate.

2. **Q: How will reviewers be instructed to consider the inclusion of People with Lived Experience (PWLE)?**
Answer: Review criteria specific to this Notice of Funding Opportunity (NOFO) can be found in Section V of the RFA. These review criteria and found under the heading "*In addition, specific to this NOFO.*"

3. **Q: Will each reviewer be evaluating all the cores and the research project? Or will different components have different reviewers?**

    Answer: All reviewers assigned to one application ("discussants") will set the range of the scores for the merit of the entire application (the "Overall" component). Then everyone on the panel (except those in conflict) will give their final scores. All discussants will be required to read the entire application so they can properly evaluate its merit.

4. **Q: In what order will the components be reviewed?**

    Research Project → Administrative Core → Resource Core → Community Engagement and Outreach Core → Overall Component

Core-related FAQs

1. **Q: Can the center/core include industry partner/collaborator?**
Answer: Yes.

2. **Q: Can projects include educational components (e.g. collaboration with the academic center and curriculum) as part of their program or implementation proposals?**
Answer: Yes. Applicants are encouraged to leverage existing resources to support the application. However, applications to this RFA may be weakened if they are dependent on resources that may lose (or need to renew) independent funding during the P50 project period.

3. **Q: Is there a preference for a resource core with a stronger external facing structure?**
Answer: The resource core must provide a resource to the wider community, but it can also be used to further the internal goals of the center. The exact structure and resulting potential impact will be considered by reviewers.

4. **Q: Who are appropriate Pilot Award PIs?**
   Answer: Pilot studies can be solicited from and awarded to any qualified individual as long as the funds are used to conduct research relevant to the center program. Preference should be given to NIH defined Early-Stage Investigators and investigators entering a new area of research. Please note that all pilots must be approved by the NICHD program officer.
5. **Q: Should the Specific Aims pages for the Administrative, resource, and community engagement and outreach cores be structured similarly to traditional research specific aims page?**
   Answer: The Specific Aims page for each core should outline the objectives and function of the cores.

Research Project

1. **Q: Should the scope of the Research Project be similar to a large R01?**
   Answer: No. The goal of the research project is not a large R01. Specifically, the Research Project should not be structured like an efficacy trial in a single condition and the Research Project should apply broadly to medical rehabilitation research.
2. **Q: Are tool development or resource development in scope of the Research Project.**
   Answer: These topics are in scope but are not the only topics in scope.
3. **Q: Can the research project include preclinical and clinical arms?**

   Answer: Yes.

4. **Q: If you are developing a tool that is clearly applicable broadly, would testing the tool in a specific condition be responsive to the research project?**
   Answer: If the purpose of the center is to develop a tool, it would be responsive to test that tool in one or more use cases. Testing in multiple use cases is likely to better demonstrate the broad applicability.