Autism Centers of Excellence (ACE) Program Frequently Asked Questions

(Originally posted 9/13/21; questions 25 through 30 added 10/08/21)

Request for Applications (RFAs)

RFA-HD-22-008: Autism Centers of Excellence: Centers (P50 Clinical Trial Optional)

RFA-HD-22-007: Autism Centers of Excellence: Networks (R01 Clinical Trial Optional)

Please check back for updates.

1. **Q: I want to establish an Autism Center or Network (RFA-HD-22-008 and RFA-HD-22-007). Where can I find the announcements?**

   A: The links to both ACE Centers and ACE Networks RFAs are available at the NIH Guide for Grants and Contracts at:

   https://grants.nih.gov/grants/guide/rfa-files/RFA-HD-22-008.html
   https://grants.nih.gov/grants/guide/rfa-files/RFA-HD-22-007.html

2. **Q: Can the Plan for Enhancing Diverse Perspectives (PEDP) exceed 1-page in length?**

   A: No, the PEDP must be one-page in length. A PEDP is required as part of the application. Applications with a PEDP that exceeds one-page will be deemed non-compliant and returned to the applicant. Please refer to the PEDP guidance materials (https://braininitiative.nih.gov/about/plan-enhancing-diverse-perspectives-pedp).

3. **Q: Is the budget limitation for Network applications $1.5 million in direct costs?**

   A: Yes. The facilities and administrative (F&A) costs, previously referred to as indirect costs, requested by the consortium participants are not included in the direct cost limitation. Please refer to NIH policy on contract/consortium F&A costs (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-004.html).

4. **Q: Are the R01 Network applications submitted as a single R01 application or submitted in parts from each collaborating site?**

   A: The PI of the Network will submit a **single** R01 application that includes subcontracts to the collaborating sites and the Data Coordinating Center.

5. **Q: May an institution apply for both an ACE Center and participate as an ACE Network with two different Principal Investigators (PIs) (i.e., one institution submits an ACE Center application with its investigator serving as the PI, but also participates in an ACE Network application either with a different PI from its institution or as a subcontract of another institution)?**

   A: Yes.

6. **Q: If one Institution proposes an ACE Center and an ACE Network application, it would be cost efficient for them share some resources, especially in recruitment and testing, although the aims and research plans for the Network and the Center projects would be quite different. Is this going to be a problem?**

   A: Each ACE Network or ACE Center application must stand alone for the purpose of review. Therefore, each application should include budget information for all aspects of the study including subject recruitment and testing. If any ACE Centers and Networks appear to be using the same resource, the NIH program staff will adjust the budget accordingly when funding decisions are made.

7. **Q: Must the ACE Center PI be a project lead for at least one project in their application?**

   A: The ACE RFA does not require the Center PI to also be a project lead for at least one project in their application. The RFA does require that Center and Network PIs contribute at least 20% effort to the ACE Center or Network, across all parts of the application.

8. **Q: May an investigator serve as an ACE Center PI and a project PI of a different ACE Center?**

   A: This is permissible as long as there is no scientific overlap between the two projects, and the total percent effort of the investigator for both activities does not exceed 100%.

9. **Q: The ACE RFAs state that one of the required measures is the Vineland II (i.e., the Second Edition of the Vineland Adaptive Behavior Scales). However, the Vineland III is now published. Should applicants propose to use the Vineland II as originally directed, or should the newest version, the Vineland III, be used?**

   A: Applicants should propose to use the Vineland III now that it has been published.

10. **Q: The ACE R01 RFA mentions that this funding opportunity solicits applications for ACE "networks" that consist of "multi-sites" focusing on a specific topic of research. Do two sites qualify as a "network" or "multi-site"?**

    A: There is no minimum or maximum number of sites required for an ACE Network application. However, the purpose of the network is to have multiple collaborating sites focusing on a specific topic of research for optimal design and conduct of studies.

11. **Q: Our Clinical Core will be drawing blood and conducting clinical and behavioral evaluations on patients, some of whom might or might not end up meeting criteria for certain behavioral protocols. Is it acceptable for the Clinical Core to have a Human Subjects section?**

    A: Yes, this is appropriate. If a Core involves working with human subjects, then it needs to address the Human Subjects issues. However, unless the Core recruits human subjects, it does not have to discuss the requirements on inclusion of women, minorities, and children.

12. **Q: What is the official due date for the ACE RFA?**

    A: The application due date for both ACE Center and ACE Network RFAs is November 9th, 2021, by 5:00 PM local time of the applicant organization.

13. **Q: Can we request an extension on the application receipt date for the ACE RFA if there are extraordinary circumstances beyond our control? What is the late submission policy for the ACE RFA?**

    A: Section IV, 4. Submission Dates and Times of both RFAs states, “Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.” The information describing when NIH will consider a late application can be found in the NIH Policy on Late Application Submission (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html), which

allows for a two-week window of consideration after the application due date. No NIH staff can give advanced permission for late submission. The applicant must include a cover letter with the application indicating why he/she is asking for the two-week window of consideration. This only applies to applications where the applicant's role is Principal Investigator but not for other roles like co-I, etc. After submission, the NIH Division of Receipt and Referral (DRR), within CSR, will review the cover letter and make a decision on whether or not to allow a late submission.

14. **Q: Will NIH accept late applications from applicants affected by COVID-19?**

    A: For applicants affected by COVID-19, NIH is taking a flexible stance for applications submitted within the standard two-week late policy window (see https://grants.nih.gov/faqs#/covid-19.htm?anchor=question55757). Applicants should include a cover letter with an explanation for the late submission. No NIH staff can give advanced permission for a late submission. The applicant must include a cover letter with the application providing an explanation for late submission (i.e., how you were affected by COVID-19). After submission, the NIH Division of Receipt and Referral (DRR), within CSR, will review the cover letter and make a decision on whether or not to allow a late submission.

15. **Q: Will Center applications and Network applications be reviewed by the same Study Section?**

    A: Since they are two RFAs, the Center and Network applications will be likely reviewed by two different Special Emphasis Panels. The members of the panels may be overlapping.

16. **Q: Can my ACE application include work in animal models (rats, mice, flies)?**

    A: The ACE RFAs do not explicitly prohibit such studies; however, participating institute priorities are focused on human subject studies.

17. **Q: I am trying to understand the type of clinical trials that will be responsive to the ACE RFAs. If I propose an intervention that does not include an assessment of efficacy, would that be considered responsive?**

    A: Only mechanistic studies or basic experimental studies with humans (BESH) studies will be accepted. Clinical trials that are designed to evaluate safety, tolerability, clinical efficacy, effectiveness, clinical management, and/or implementation of pharmacologic, behavioral, biologic, surgical, or device (invasive or non-invasive) interventions are nonresponsive to this funding

announcement. Additional information and examples can be found here: https://grants.nih.gov/policy/clinical-trials/case-studies.htm and https://grants.nih.gov/policy/clinical-trials/besh.htm.

18. **Q: Can I include investigators from foreign institutions in my application?**

    A: "Foreign components," as defined in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm), are allowed in these RFAs. Non-domestic components of U.S. organizations, as well as foreign institutions and entities, are not eligible to apply to these RFAs as the primary applicant.

19. **Q: Does the ACE Centers RFA allow for a multiple-PI option?**

    A: Yes. However, the application must name one of the PD(s)/PI(s) as the overall Center Director.

20. **Q: Where in the application can I address the impact of COVID on the productivity of my current ACE Center/Network?**

    A: You can include this information in the Summary of Progress in the Overall section of the renewal application.

21. **Q: Where in the application can I address the impact of COVID on my own productivity including limited scientific publications?**

    A: You can include this information in your Personal Statement in the NIH Biosketch. More information can be found here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-180.html

22. **Q: I would like to establish an ACE Center to provide evidence-based services for individuals with ASD and their families. Is this acceptable?**

    A: No. Please refer to the information in the Purpose section of the ACE Centers (P50) RFA.

23. **Q: Our research team planned to propose a Clinical Core in our ACE Center application to focus on recruitment, retention, and phenotyping. However, we noticed that the RFA stated that the Dissemination and Outreach (D and O) Core needs to describe plans to "ensure successful recruitment and retention of study participants." Does this mean that recruitment and retention must occur through the D and O Core?**

A: The P50 Centers RFA does not require the D and O Core to be involved in the direct recruitment and retention of study participants. However, the D and O Core needs to describe plans for a number of activities, including those that promote recruitment and retention. In addition to the required Administrative Core and the D and O Core, the RFA allows the applicant to propose up to 2 more Cores.

24. **Q: How does my Early-Stage Investigator (ESI) or New Investigator (NI) status change if I am part of an ACE Center or Network award?**

    A: If an ESI or NI serves as the PD/PI for an ACE Center or Network application, the individual will lose his/her ESI or EI status when the award is made. If the ESI or NI is the lead of a project or core, but not the PD/PI for the overall application, the individual will retain ESI or NI status when the award is made.

25. **Q: What is considered an intervention?**

    A: According to the NIH Office of Intramural Research's FAQs: NIH Clinical Trial Definition page (https://oir.nih.gov/sourcebook/intramural-program-oversight/intramural-data-sharing/guide-fdaaa-reporting-research-results/frequently-asked-questions-nih-clinical-trial#:~:text=An%20intervention%20is%20defined%20as,behavioral%20processes%20and%2For%20endpoints): "An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies."

26. **Q: What is a mechanistic clinical trial?**

    A: The goal of mechanistic studies is to address basic questions and to interrogate concepts in biology, behavior, and pathophysiology that will provide insight into understanding ASD. These studies may seek to understand a biological or behavioral process, or the mechanism of action of an intervention. This RFA allows mechanistic clinical trials as well as biomarker studies that may provide information about physiological function, target engagement of novel therapeutics, and/or mechanisms of therapeutic response.

27. **Q: One of our center projects will focus on validating a screening tool (screener) for autism. We will administer the screener to a large population and determine whether the screener detects those who later meet the diagnostic criteria for autism. Does this study meet the NIH definition for a clinical trial? Is this study responsive to the ACE RFAs?**

    A: Based on the limited information stated here, your project does not appear to meet the definition of a clinical trial (CT) as provided in NIH CT Case #7a on the NIH Definition of Clinical Trial Case Studies (https://grants.nih.gov/policy/clinical-trials/case-studies.htm) and is responsive to the RFA. However, the "official" CT determination is made on the actual submitted application. The details provided could change the determination. Also, even if ONE SMALL PART of this study is a CT (even only a small part of a minor aim), the whole application will be designated as CT. For example, if the application you submitted includes an additional component assessing the effect of screening on the participants, then this application will be designated as a clinical trial.

28. **Q: One of our center projects will use an intervention as a probe to evaluate mechanisms of ASD. Is this study responsive to the ACE RFAs?**

    A: Yes. This would be considered a mechanistic clinical trial, as described as in question 26 and is allowed.

29. **Q: Can I submit an application with direct-costs over $1.5 million per year?**

    A: No. An application proposing direct costs exceeding $1.5 million per year will be deemed non-compliant and returned to the applicant.

30. **Q: The ACE Network RFA mentions a plan for network evaluation. Where should this plan be included in the application?**

    A: A plan for network evaluation should be included under "administration and operation of the ACE network" within the "research strategy" section.

Please send additional questions to Alice Kau at kaua@nih.gov. This FAQ list may be updated as necessary.