Frequently Asked Questions for NINR R34 FOA

Q1: Who is eligible to apply for the R34?
A1: It is the responsibility of the applicant organization to select the individuals who have the appropriate expertise to manage the scientific and administrative aspects of the project. The level of expertise should be similar to that needed for other NIH R-series applications.

Q2: If the application does not propose collecting feasibility and pilot data, will it be considered non-responsive to this FOA?
A2: Collecting feasibility and pilot data to inform the design and execution of a high quality clinical trial is required. If there is already sufficient feasibility and pilot data to meet this goal, the applicant should consider a different activity code, such as an R01.

Q3: Must the R34 application propose a clinical trial be carried out as part of the R34?
A3: Yes. This R34 planning grant is intended to pilot test approaches that can inform the design of the subsequent clinical trial (the subsequent clinical trial should be described in the attachment “Future Clinical Trial Description”).

Q4: The R34 review criteria include additional criteria for clinical trials. Do these criteria apply to the clinical trial that will be carried out with the R34 support?
A4: Yes, these review criteria apply to the R34-supported clinical trial. As stated in the FOA, applications should demonstrate that feasibility and pilot studies are both necessary and sufficient to permit definitive decisions about the design of the future clinical trial.

Q5: What should be included in the “Future Clinical Trial Description” attachment if the design of full-scale trial is not final?
A5: The purpose of the attachment is to provide context for the goals of the R34 award. The reviewers will use this information to evaluate how the feasibility and pilot data to be collected will contribute to the goals of the full-scale trial and inform the design of the future clinical trial. The “Future Clinical Trial Description” should contain enough information for the reviewers to evaluate 1) the hypothesis of the trial; 2) the public health impact of the trial; 3) whether the planned design of the trial will address the hypothesis; 4) how the information gathered through the R34 award will contribute to the design of the trial; and 5) whether the information gathered with the R34 award is both necessary and sufficient for the R34 applicant to make the final decisions about the trial design.

Q6: Are R34 studies that propose to determine efficacy responsive to this Funding Opportunity Announcement (FOA)?
A6: No. The intent of the NINR R34 FOA is to provide support to collect information needed to complete the design of a clinical trial with public health importance. Since this FOA is designed to support feasibility and pilot studies, an efficacy-based power analysis is not appropriate or necessary. The sample size needed to pilot the proposed approach, including the assumptions used when estimating the sample size, should be detailed in relation to the analysis plan. Applicants must detail their plans for determining feasibility and for evaluating if the data warrants moving to a full-scale trial.
Q7: I have developed a clinical trial and need support to identify clinical sites, finalize the protocol and write the manual of procedures. Is the NINR R34 appropriate?

A7: Probably not. The NINR FOA is specifically tailored to support research addressing gaps in knowledge necessary to complete the design of a trial with public health impact. An already-developed trial would not be suitable for NINR R34 support.

Q8: If I am an Early Stage Investigator (ESI) and am awarded an R34, will I lose the ESI status?

A8: No, an R34 does not count against the ESI status. You will still possess ESI status should your R34 application be awarded. Please see the NIH FAQs related to ESI [https://grants.nih.gov/policy/early-investigators/faqs.htm](https://grants.nih.gov/policy/early-investigators/faqs.htm)

Q9: If I qualify as an Early Stage Investigator (ESI), will I be given special funding consideration?

A9: No, the R34 is not eligible for ESI special funding consideration.

Q10: Where is my R34 application reviewed?

A10: The R34 applications are reviewed by a committee that is convened by the NINR Scientific Review Branch. Additional review criteria (specified in the FOA) will be applied.

Q11: Can I submit an R34 and an R01 for the same trial simultaneously?

A11: This is not allowed. An R01 application for a clinical trial that lacks sufficient information to justify its design would not be competitive. On the other hand, reviewers are likely to look unfavorably on an R34 application if there is already sufficient information to design a competitive full-scale trial. In the latter case, one should submit an R01 application directly.

Q12: Can I submit two R34s for the same planned follow-up trial?

A12: No. If you need two R34s, neither one will meet the criterion of “both necessary and sufficient” to design the follow-up trial.

Q13: If I submitted an R01 application for a clinical trial and the reviewers said that I needed more data to justify or show feasibility of one aspect, may I apply for an R34 for that trial?

A13: Yes, if the questions you are asking meet the criteria of the NINR R34 FOA, you may apply, even if you have already applied unsuccessfully for an R01. The R34 will be a new application; however, following completion of the R34, the follow-up R01 application will be considered a resubmission (A1), if the resubmission time frame has not expired.

Q14: How do I decide whether to submit an R34 or an R01 for a small multi-site intervention trial?

A14: If you have all the information that you need to design the trial, you should use the R01 activity code. The NINR R34 FOA is specifically designed to allow investigators to collect information needed to enhance the quality of the trial design and the likelihood of successful implementation to meet the objectives of the trial.

Q15: Are studies involving vertebrate animals appropriate to be conducted under this FOA?

A15: No. The NINR R34 FOA is intended for human subjects research.
Q16: I serve on study section and am eligible for continuous submission status. May I submit my application late?

A16: Yes, see the NIH Continuous Submission page for full details including how to check your eligibility, and the associated Frequently Asked Questions. If you have further questions about this, please contact the Scientific Review Officer listed in the FOA.

Q17: Are there any additional instructions for the application?

A17: Follow the instructions in the SF424 Application Guide as modified by the instructions in the FOA. Note that the FOA requires an additional attachment - the “Future Clinical Trial Description.” Detailed information is contained in Section IV.2. Applications may not be reviewed if they do not contain the required information. Please read the entire FOA for all requirements.
To view a webinar about the FOA, please visit: https://youtu.be/vRoMKPyGYKw.

Q18: Are appendices permitted?

A18: No, appendices are not permitted. NIH issued NOT-OD-16-129 on August 12, 2016 eliminating most appendix materials. The required file, “Future Clinical Trial Description.pdf” should be included as an attachment. It should be included under the “Other Project Information” section of the application, should be bookmarked for easy access by reviewers, and may not exceed 3 pages. The detailed Protocol Synopsis in the PHS Human Subjects and Clinical Trials Information section inside the R34 application is used for the description of the clinical trial proposed for support with R34 funding, not for the clinical trial outlined in the attachment “Future Clinical Trial Description.”