Frequently Asked Questions (FAQs)

ACTG Request for Applications
Small Clinical Trials Advancing HIV Remission and Cure

11Jan2022

1. Budget
    a. Is a budget required?
    The proposal investigators do not need to complete a budget for the trial. The funding will be managed within the ACTG to avoid the need for additional subcontracting with the sites.
    b. How much funding is available?
    The funding will support the costs of conducting the clinical trial at a small number of ACTG sites and will go to these sites to support enrollment. The funding will be managed within the ACTG to avoid the need for additional subcontracting with ACTG sites. Funding will include costs for tissue sampling as well as the collection of other types of biospecimens and pharmacologic testing as needed. There will be a small amount of support for the proposing investigators who will lead the protocol team- with 25% of NIH cap, divided between the protocol team leadership. We anticipate that each trial will cost between 1-2 million dollars. No budget information is required with the application. A schedule of events for the clinical trial may be included as an appendix. \
    c. Can you confirm the F&A rate that is provided along with the salary support funding?
    The ACTG allows for the federally negotiated institutional IDC rate.

2. How large can the proposed trial be for this funding mechanism?
    a. *We anticipate that these will be small trials to be conducted at 1-3 ACTG sites with up to 30 participants. Larger clinical trials can be submitted through the standard ACTG concept proposal pathway (https://submit.mis.s-3.net/).*

3. Where will the proposed studies be conducted?
    a. *The proposed trials will be conducted at core ACTG sites, both US and non-US. The proposing investigators will lead the trial as protocol chair/co-chairs.*

4. Will the program support the development of the intervention for testing?
    a. *The proposed interventions need to be readily available for testing or have a plan to access it for trials. This funding mechanism does not support the development, GMP manufacturing, or pre-clinical safety testing of new products*

5. Who will be the sponsor and IND holder for the study?
    a. *The Division of AIDS will be the sponsor and hold the IND.*

6. Can an investigator chair the protocol even though they already chair other ACTG protocols?
    a. *Yes.*

7. The RFA states that the "Research Plan" is limited to 6 pages, does this include the investigators' accomplishments ("prior and current experience with specific HIV remission and cure studies….") as well as the "proposed scientific contributions to the ACTG…"? Or are these to be included outside the 6 pages for the Research Plan? What PHS 398 documents are to be submitted with the application?
    a. *See revised RFA dated 10Aug2021, which more clear indicates the necessary information and documents to be included.*

8. Are the cited references counted in the six-page research plan?
    a. *The references are not included in the 6-page limit.*

9. What margins should be used for the Research Plan?
    a. *One-half inch margins all around can be used.*

10. To whom should the application be submitted?
    a. *The application should be submitted through the proposal submission that will be available at https://actgnetwork.org/submit-a-proposal/ by 1 April.*

11. What would be appropriate to include under the 'Accomplishments' section of the PHS 398 research strategy section?. Should I put preliminary data that supports the design of my trial here, or is this intended to be a list of accomplishments by the study team?
    a. *How an investigator uses the Accomplishments section will vary by investigator and proposed trial. Examples of information that may be relevant include but are not limited to:*
    1) Translation research success of the investigator or team in a similar or related area
    2) Published or preliminary data applicable to proposed project
    3) Translational clinical trials experience of the investigator or the team

12. Should a specific aims page be included?
    a. *There is no need for a separate aims page. The primary and secondary objectives of the clinical trial should address the aims/objectives of this translational research.*