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.

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. This funding mechanism does not support manufacturing or pre-clinical safety testing.

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.