**Clinical Trials Staff Visit**

In order for the Institute to consider accepting your application, the proposed research must be relevant to the NHLBI mission, must provide valuable information to the existing knowledge base and will have public health applicability. This checklist is designed to help you prepare for your staff visit. Details about the visit can be found at <http://www.nhlbi.nih.gov/funding/policies/500kweb.htm> .

Well in advance of the receipt date you hope to submit your application, plan a staff visit with NHLBI program and review staff. This visit can be in person, or by teleconference. This is your opportunity to ask questions and get feedback on your proposed research and discuss submission and review issues with NHLBI staff.

Ensure that you plan to include in your application, and are prepared to discuss during the staff visit, the following items.

a. Study Design and Methods

* + 1. Study population
    2. eligibility, inclusion/exclusion criteria
    3. enrollment plan, feasibility
    4. primary and secondary endpoints
    5. methods of randomization
    6. important considerations for sample size and power calculations
    7. methods and frequency of data collection and entry
    8. monitoring accuracy of data collection
    9. quality control procedures including training of study personnel
    10. plans for statistical analysis
  1. Study Organization (Verbal descriptions are necessary, but a flow chart or diagram of the study organization is a plus!)
  2. Human Subjects (patient safety and confidentiality, informed consent, adverse event monitoring and reporting plan, ethical considerations)
  3. Data Safety and Monitoring Plan, DSMB composition (do not name individuals on new applications)
  4. Gender/Minority/Children (be sure to include requested %-tables)

Details can be found at: <http://www.nhlbi.nih.gov/funding/policies/clinical.htm>

Submit required materials and letter requesting approval to submit a greater than $500K clinical trials grant application to the Division Director of the relevant program division according to the [Guidelines for Applications with Direct Costs of $500,000 or More in Any One Year](http://www.nhlbi.nih.gov/funding/policies/500kweb.htm). The materials should include sufficient information about the specific aims of the research (including subprojects), the significance and/or potential impact of the research on public health or health care of the research, annual direct, and total direct, costs and total costs, and key investigators to be no longer than 5 pages. This will enable the Institute to make an informed decision about whether or not to accept a proposed application. Institute staff can guide you further about what to include in your letter.

If NHLBI agrees to accept your application for review, you will receive a letter of approval to submit with a budget cap, prior to the receipt date. You should not wait until you receive this letter to work on your application, since it may arrive as close as 2 weeks prior to the receipt date. You must include a copy of the approval letter with your application when it is submitted to the Center for Scientific Review (CSR). If it is not attached, CSR will return the application and NHLBI will not intercede on your behalf.

If you are planning a Phase III multi-site randomized clinical trial with greater than $500,000 in direct costs in any year, you must plan to have a separate Data Coordinating Center (DCC) application. This application will be linked to the parent (Clinical Coordinating Center, CCC) application and reviewed together, as one project. The Research Strategy section of the CCC or DCC application may not exceed 12 pages.

If needed, you may include an additional linked application for a Core Lab or Imaging/Reading Center. Core/Imaging Center applications will also be linked and reviewed with the parent and DCC applications. The Research Strategy of an application for a Core should not exceed 6 pages.

Each linked application should include its own face page, budget, budget justification and biosketches. Each should have the same title and abstract. Only the parent application should include the scientific background and significance sections; the linked DCC and core applications need only describe their specific functions and do not need to repeat the science. They may, however, reference the science in the parent application.

Plan to include in the Appendix: informed consents, a copy of the clinical protocol, letters of commitment from enrollment sites, industry, consultants and other collaborators. No more than 3 relevant published manuscripts (only when a free, online, publicly available journal link is not available) should be included with the Appendices. It is important that the page limitations of the Research Strategy section of the application are not circumvented by materials included in the Appendix.

Send 2 additional copies with Appendices to:

Keary Cope, Ph.D.

Clinical Studies and Training Scientific Review Group

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Approximately 1 month after receipt of the application, you will receive an acknowledgement letter. Post-submission supplemental data are no longer accepted. Certain exceptions described in NOT-OD-10-115 may apply.