

Name of Principal Investigator:



NIH NHLBI ARDS Network
Proposals for Sub-Studies or Ancillary Studies

TITLE OF PROJECT:

PRINCIPAL INVESTIGATOR

Name (last, first):

Degree (s):

Position:

Mailing Address:

Institution:

Department, Service, Laboratory, or Equivalent:

Major Subdivision:

Telephone:

Fax:

E-mail:

Start and Stop Dates of Proposed Project:

ARDS NETWORK SPONSOR

Name (last, first):

Degree(s):

Position:

Mailing Address:

Institution:

Department, Service, Laboratory, or Equivalent:

Major Subdivision:

Telephone:

Fax:

E-mail:

Name of Principal Investigator:

Please review these instructions before preparing a proposal. Please delete these instructions before submitting a proposal.

Definitions

“Sub-studies” are investigator-initiated studies that utilize previously collected data or samples from ARDSnet clinical trials. The studies may be related to the clinical issues addressed in the original trial, but the existing data and samples may also be used to address other questions.

“Ancillary studies” are investigator-initiated studies that involve an extension of the main goals of an ARDSnet trial, and usually require collection of additional data or samples. Additional funds, independent of the ARDSnet contracts, are generally required for ancillary studies. Proposals for ancillary studies should include information regarding support for additional efforts by ARDSnet people, including the Clinical Coordinating Center, if needed. Ideas for ancillary studies must be presented to the full Steering Committee for discussion and approval before submitting a grant proposal to the funding agency. The effect of the ancillary study on the main study and its scientific value and validity will be determined by the Steering Committee. Upon approval of the concept, the ancillary study proposal will be reviewed by Natural History or Pathogenesis as appropriate.

1. Submit sub-studies at least 2 weeks before regularly scheduled meetings of the Natural History or Pathogenesis Committees (<http://www.ardsnet.org/event>).
2. Ancillary studies require review by the ARDS Network Steering Committee after review by the Natural History or Pathogenesis Committee. Therefore ancillary studies should be submitted at least 5 weeks before regularly scheduled meetings of the Natural History or Pathogenesis Committee.
3. Biographical Sketches are required for all key personnel who are not ARDS Network members.
4. The research plan (Sections A-D) should be concise and limited to no more than 6 pages. The research plan includes specific aims, background and significance, preliminary studies, and research design and methods.
5. The research plan should describe in detail any assistance requested from the ARDSnet Coordinating Center, i.e., generation of data sets, data analysis, etc.
6. For submissions to the Natural History Committee, the research plan should indicate if the proposed sub-study requires collection of new data. If so, the research plan should describe the resources available to do this and how associated expenses will be paid.
7. For submissions to the Pathogenesis Committee, the research plan must explicitly indicate the amount of patient-derived biological material requested, i.e., mL of plasma or urine or mcg of DNA.
8. All proposals should include a statement confirming that all investigators named on the project have read the proposal and agree to participate.
9. If analyses are to be conducted by investigators independent of the ARDSnet Coordinating Center, the Coordinating Center will verify selected aspects of the analyses during the review process. Therefore, if investigators plan to conduct their own analyses, they are encouraged to discuss the analytical plan with the Clinical Coordinating Center in advance. This will help to avoid delays during the review process.
10. Appendix material is not encouraged.
11. Submit proposals ELECTRONICALLY to Andrea Harabin, Ph.D. (harabina@nhlbi.nih.gov).

Information Regarding Proposed Sub-studies:

Name of Principal Investigator:

- Institutional Review Board approval will be required for all sub-studies and ancillary studies.
- For sub-studies approved by the Pathogenesis Committee, the ARDSnet Repository cannot release any samples until the investigator obtains and supplies any required IRB approval to the Committee.
- For sub-studies approved by the Pathogenesis Committee, investigators can only perform those measurements specifically approved by the Committee, and they must return unused residual samples to the ARDSnet Repository.
- It is expected that the results (positive or negative) of all approved sub-studies, including those considered non-publishable by the study's investigators, will be presented to the ARDSnet Steering Committee in a timely manner.
- After approval of sub-studies, the lead investigator should email a concise (one paragraph) summary of progress at 6 month intervals.
- For sub-studies that involve analyses of existing data, investigators should submit a manuscript to the Publications Committee within one year of approval.
- The ARDSnet Publications Committee must review all publications resulting from the sub-study prior to submission for publication in any format (including abstracts).

CHECKLIST

- Instructions for preparing sub-studies and ancillary studies have been reviewed.
- Analytical plan has been discussed with ARDSnet Coordinating Center.
- All investigators have agreed to participate in this project.
- The statistical section includes sample size calculations where appropriate.
- Scientific sections A – D are prepared with font size 11 or larger.
- Scientific sections A – D are ≤ 6 pages in length.
- Institutional Review Board approval will be obtained.
- Biosketches are included for *key people who are not* members of ARDSnet.

Name of Principal Investigator:

ABSTRACT

State the broad, long-term objectives and specific aims. Describe concisely the research design and methods for achieving the goals. This abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application.

PERFORMANCE SITE(S)

Institution

City

State

KEY PERSONNEL

Name

Institution

Role on Project

Name of Principal Investigator:

SCIENTIFIC PROPOSAL (Sections A-D limit 6 pages)

- A. STATEMENT OF HYPOTHESIS AND SPECIFIC AIMS
- B. BACKGROUND
- C. PRELIMINARY DATA
- D. RESEARCH DESIGN AND METHODS
 - 1 Study Design
 - 2 Data Needed for this Study
 - 3. Inclusion and Exclusion Criteria
 - 4. Endpoints
 - 5. Statistical Considerations (sample size, analytical plan)
- E. ASSISTANCE NEEDED FROM THE COORDINATING CENTER.
If needed, please explain why you need information that could be used to identify specific patients. Also, specify which members of the study team should receive this information. Include information regarding need for identifiable patient information.
- F. BIBLIOGRAPHY (suggested limit of 25 references)
- G. BIOSKETCHES (of *key personnel who are **not** ARDSnet members*)