

RESEARCH AGREEMENTS WITH COLLABORATORS

1. OBJECTIVE:

Describe how research/clinical trial agreements between the Atlanta Research and Education Foundation, Inc. (AREF) and Collaborators are prepared, reviewed and executed. With only a couple of exceptions, all clinical trials conducted at the Atlanta VA Medical Center must be negotiated using one of the VA's Cooperative Research and Development Agreements (CRADAs).

2. RESPONSIBILITIES:

- a) The Principal Investigator (PI) or designee is responsible for contacting the AREF Contracts/Grants Administrator and informing him/her of his/her interest in participating in an industry-sponsored clinical trial.
- b) The AREF Contract/Grants Administrator, with the assistance of VA Regional Counsel, is responsible for: a) determining the appropriate CRADA model to use during study negotiations; b) the legal review and final negotiation of the CRADA
- c) The AREF Clinical Trials Financial Analyst is responsible for the review and final negotiation of clinical trial study budgets.

3. PROCEDURES:

- a) The PI is expected to provide the AREF Contract/Grants Administrator with the following Sponsor information:
 - I. Sponsor/CRO's name and address
 - II. Contact Person
 - III. Telephone Number
 - IV. Fax Number
 - V. Email Address
 - VI. Title of Study
 - VII. VA HIPAA Authorization form (www.atlaref.org)
 - VIII. Financial Conflict of Interest Statement form (www.atlaref.org)
- b) The PI is required to provide the AREF Clinical Trials Financial Analyst with a copy of the study protocol as well as a completed Assessment of Clinical Impact Form (www.atlaref.org), outlining the obligations of the study for the Atlanta VA Medical Center.
- c) All research projects administered by AREF must have a signed agreement between the Collaborator and AREF. R&D Committee approval may be sought simultaneously while establishing the AREF contract.
- d) As a general rule, no research funds should be expended until Emory IRB and R&D Committee approval has been obtained. However, reasonable and usual preliminary costs for project planning prior to approval are allowable according to VA policy. For AREF administered studies, PIs must have a signed agreement before study activities are initiated (defined as enrollment of the first study subject).