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).

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