RESEARCH AGREEMENTS WITH COLLABORATORS

1. **OBJECTIVE:**
   Describe how research/clinical trial agreements between the Foundation for Atlanta Veterans Education and Research Foundation, Inc. (FAVER) and Collaborators are prepared, reviewed and executed. With only a couple of exceptions, all clinical trials conducted at the Atlanta VA Health Care System (AVAHCS) 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 FAVER Grants and Contracts Specialist and informing him/her of his/her interest in participating in an industry-sponsored clinical trial.

   b) The FAVER Grants and Contracts Specialist, 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 FAVER Grants and Contracts Specialist, with input from the PI, is responsible for the review and final negotiation of clinical trial study budgets.

3. **PROCEDURES:**
   a) The PI is expected to provide the FAVER Grants and Contracts Specialist 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. Copy of the study protocol
      VIII. Estimated number of subjects expected to be enrolled at AVAHCS.

   b) The PI is required to provide the FAVER Grants and Contracts Specialist with the following documents:
      I. Completed Assessment of Clinical Impact Form outlining the obligations of the study for the Atlanta VA Health Care System. (https://faver.foundation/apps/clinical_impact/)
      II. Financial Conflict of Interest Statement form. (https://www.atlanta.va.gov/Docs/Research_coi_form_final.pdf)

   c) All research projects administered by FAVER must have a signed agreement between the Collaborator and FAVER. R&D Committee approval may be sought simultaneously while establishing the FAVER contract.

   d) As a general rule, no research funds should be expended until the IRB of Record and R&D Committee approval have been obtained. However, reasonable and usual preliminary costs for project planning prior to approval are allowable according to VA policy. For FAVER administered studies, PIs must have a signed agreement before study activities are initiated (defined as enrollment of the first study subject).