6. c Data Plan

It will be the policy of the center to welcome collaboration with outside investigators. To gain access to data collected directly by the center (exposure data), outside collaborators are asked to submit a complete research plan to the center director. The plan should include the data requested, and the planned use for the data. The submitted plan should follow the QMP requirements for the QAPP or research plan required of internal investigators. (See QMP) To assure that all publications using center data are of comparable quality, the center director and relevant project PIs will evaluate the request for scientific merit. They will also review ongoing studies to make sure the proposed research does not overlap with ongoing research. Once the plan is approved and a data use agreement is signed by both parties, data will be provided in SAS format to the outside collaborator. We will make the data and associated documentation available to users only under a data-sharing agreement that provides for: (1) a commitment to using the data only for stated research plan and not to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed. All variable labels, formats, units and notes required to use the dataset will be available by running SAS Proc Contents and SAS Proc Means. Permission to use the data will be limited to the approved research plan. Should the outside collaborator wish to expand the research, an amended plan must be submitted for approval. All outside collaborators working with center generated data must follow the requirements of the QMP, specifically requirements for internal center peer review prior to publication.

No health outcomes data is being collected by the Center. All health outcomes data to be used by the Center will be provided under data use agreements that limit our use of the data to what is described in this proposal. We are required to go back to the original source and apply for permission should we wish to expand or modify our studies. (These data are highly regulated and have IRB and HIPPA limitations placed on them by the source Institution). Our data use agreements with these institutions prohibit us from distributing the data to other parties. To gain access to health outcomes data from outside sources; VA, VIVA, Framingham, National Study, the collaborator must file a request including proposed research plan and required data with the original generator of the data, with a copy to the Center Director. Each institution that has generated the health outcomes data has a distinct process that is specific to the institution’s research, IRB and HIPPA administration. These processes may change as regulations or institutional interpretation of regulations change. In addition to following the requirements of the Center QMP, outside collaborators must follow the quality management practices of the institution providing the health data. Proposed research plans for Health Outcomes data must include exemption determinations or IRB approvals from the outside collaborators institution. These documents are required to file amendment requests from the data generator’s IRB for the proposed project. Once the Research Plan is approved by the data generating institution and a data use agreement is in place with the data generating institution for health outcomes data and the center for exposure data, the center will provide the requested exposure data. The health outcomes data will come directly from the data generating institution.
Supplemental data provided in support of accepted publications in peer reviewed journals can be obtained from the relevant journal.