ABOS RESEARCH POLICY

A. Review and Approval of Research Proposals

1. Anyone seeking to use ABOS data for research purposes must submit a research proposal to the Research Committee. The Research Committee will review and determine whether or not to approve any and all research proposals requesting use of ABOS candidate data.

2. All research proposals will include:

   (a) The questions the investigator(s) wish to answer; i.e., research design, including question(s) to be addressed;

   (b) A clear, narrow and testable hypothesis;

   (c) A request for data specific to one study without the intention for use of subsets within the dataset for other studies;

   (d) A description of the data sought (in table format);

   (e) A description of how data will be used if study proposal is approved;

   (f) A literature review to support the question(s) being asked;

   (g) The research methodology and protocols to be followed (including those to protect the confidentiality of the data);

   (h) The personnel who will be involved in the research and granted access to the data and results; description of their role and or involvement in the proposed project (this should include the ABOS Director Liaison [see #10 below] who will review and pre-approve a manuscripts or presentations prior to final approval from the Committee);

   (f) The anticipated timeline for completion of the project, including the time to complete data analysis from time data is received, the time to prepare publications, manuscripts, presentations, and the anticipated date that the data is to be deleted or returned to ABOS;
(g) A description of the financial support for the project, including any request for funding or administrative support by the ABOS;

(h) The anticipated form of the results displayed in proposed tables/figures;

(i) The anticipated scope of dissemination, publication (targeted journal), targeted presentations and reuse of the results and data in any other forum; and a proposed timeline for said dissemination.

3. The Research Committee will evaluate a research proposal in accordance with the criteria set out in Section A.4.

4. Research proposals shall be evaluated in accordance with the following criteria:

   (a) Is the proposal consistent with the purpose and policies of the ABOS?

   (b) Will the proposal potentially create any actual or perceived conflict of interest?

   (c) Will the proposal violate any legal requirements or create any legal risk for the ABOS?

   (d) Does the proposal require an acceptable level of ABOS staff support and/or funding?

   (e) Is the proposed research design and methodology appropriate and likely to yield reliable and useful results?

   (f) Does the proposal state a clear, narrow, and testable hypothesis?

   (g) Does the proposal state a focused aim and hypothesis for how the requested dataset will be used?

   (h) Have there been similar studies approved by the Research Committee in the past 5 years? Have those similar studies ended in publication? If, not are publications forthcoming?

5. The Research Committee must approve all research proposals using the ABOS database.

6. Should a PI wish to pursue use of the data prepared for one approved study for another study, then a new proposal must be submitted.
7. The Research Committee considers only retrospective proposals with requests for data already collected by the ABOS database.

8. No proposals for adding new data to the already collected set of data will be considered. Requests for data that will enhance the existing study need to be made in writing and will be considered by the Committee.

9. Requests for prospective data collection are not accepted.

10. The Director Liaison, the Research Chair, and the Executive Medical Director must approve publication or presentation of all research results. If there is a concern of a conflict of interest, it will be sent for full Research Committee approval.

B. Terms and Conditions for Use of ABOS Data in Research Projects

1. Access to and analysis of ABOS data shall be limited to those individuals identified in the research proposal with the prior express written consent of the ABOS. The PI is responsible to ensure that access to the data is allowed only as identified in the research proposal.

2. All provided data will be de-identified in accordance with HIPAA requirements. ABOS will not disclose any personally identifiable information within the meaning of HIPAA.

3. The researcher will provide written assurance that it is in compliance with all applicable protocols for the protection of human participants in research projects. In particular, where data is collected by the ABOS specifically for the research project, the researcher will provide written documentation for IRB approval of the research design and provision for participant consent or, in the alternative, written demonstration that such requirements are not applicable.

4. The researcher executes a Research Agreement (in the form attached as Exhibit A).

5. The researcher shall provide progress reports in accordance with a mutually agreed upon project timeline and failure to meet the timeline may result in forfeiture of project approval and use of ABOS data for the proposed project.

6. ABOS shall own all rights and interests in the data, analyses of the data and reports and publications using, referencing and/or containing the
data and/or analyses of the data unless otherwise agreed in writing by the ABOS.

7. All analyses, reports and publications using, referencing and/or containing data and/or analyses of the data shall be made available to ABOS for its review prior to any dissemination or publication to third parties and any such analyses, reports or publications may not be disseminated or published to third parties without ABOS’s express prior written approval.

8. All analyses, reports and publications approved for publication will contain appropriate references as to the source of the data and disclaimers that the views expressed in the publication are not the views of the ABOS unless authored on behalf of the ABOS or with the prior express written permission of the ABOS.

9. All data shall be deleted (destroyed) upon the termination of the research project and the researchers will not retain any copies of the data. The Principal Investigators will complete an attestation document to this effect as provided by ABOS.

10. No analysis, report, paper or article using or referencing ABOS data shall be prepared for a Director’s personal gain/benefit or otherwise; this would be in violation of the ABOS’s Conflict of Interest Policy.

11. Failure to comply with any of the policies set forth above in regards to use of the ABOS data will result in disqualification of the PI from any protocol submissions for a period of 3 years?