Standard Operating Procedures (SOP) for Preparing AACC Academy Documents

This SOP outlines the process of developing clinical documents under the AACC Academy. While the procedure below refers to Guidance Documents specifically, the major milestones will remain the same across all document types. Differentiation from the below process for other document types can be found in Appendix A.

PROCEDURES:

1. **Selection of topics for guidance documents**
   Oversight of guidance documents is under the direction of the AACC Academy's Content Development Committee (CDC) and approved by the Academy Council. On an annual basis, the Council will review potential topics and prospective authors for guidance document preparation. If a topic is deemed significant enough to warrant a guidance document, the Council will identify a prospective author and invite them to chair the guidance document and submit a proposal. Any member of the Academy may also submit recommendations or proposals for topics to the Council. Proposals should contain the following components:

   - Title
   - History, statement of need, motivation and significance of topic
   - Potential Author list (optional at this stage)
   - List of questions to be answered (optional at this stage)

   All proposals will be evaluated by the Council, or designee, based on the following criteria:

   1) relevance and importance of the proposed topic as a guidance document;
   2) track record of the proposed author (knowledge about the subject and prior record, if any, in writing this style of paper).

   The review process may include constructive comments for improving the proposal and a recommendation to invite, resubmit or reject. Based on the review results, a decision is made by the Council and communicated back to the proposers/authors.

2. **Writing Group selection**
   Guidance Document chairs may select their writing group with approval of the Academy Council. Writing groups should consist of typically 4-6 authors or more, including at least one clinician, from multiple institutions.

   Authors are not required to be Academy fellows, though it is preferred.

   When submitting a writing group to the Council for approval, document chairs should submit a complete author list and CVs and Conflict of Interest (COI) disclosure forms for all authors. The CDC will review all CVs and COI forms first and then send recommendations to the Council for their approval and/or discussion.

3. **Role of the Content Development Committee**
   The CDC was formed to oversee the development of Academy documents. The CDC serves as a resource for each writing group, with a committee liaison assigned to each document. CDC

members communicate with document chairs to ensure they stay on track, follow all steps of the SOP, and complete their documents in a timely manner. The CDC reviews all materials prior to Council submission and provides recommendations.

4. **Review process for guidance documents**
In the case of a positive decision on the proposal, the guidance document will be invited. Positive review of the proposed guidance document and invitation for submitting the full manuscript should not be interpreted as acceptance of the full guidance document manuscript. Each completed guidance document will undergo a separate peer review process handled by the Council, or designee. A period for public review and comment will occur for all guidance documents. The comments received during the public comment period must be addressed before the document is approved by the Academy Council. The acceptance/rejection decision will be made based on criteria defined by the Council. A more detailed description of the review process is found in Appendix C.

5. **Instructions for Authors**
Guidance documents should include a statement that it is expert opinion. Conflicts of interest should be included in all guidance documents. The recommendation for the length and preparation of the document is as follows: Up to 20 double- spaced pages, Calibri font, 11 point font size, excluding figures, tables and references; the total number of tables and figures up to 7, and the total number of references up to 50. Suggested format is an Abstract at the beginning, section headers that match the approved focus questions, and each section ends with key summary points or recommendations for each focus question. Recommended parameters are flexible based on topic and publication requirements of the Journal the paper is submitted to.

6. **Suggested timeline for preparation of Academy documents**: ~12-15 months
Begins after topics and document chairs have been identified. All timeframes are suggested and flexible based on circumstances.
   a. Guidance document chair proposes their committee. Proposed committee is reviewed by the AACC Academy Council – 2 weeks suggested.
   b. Committee members are invited to join the project – 1 month suggested (for invitations and responses).
   c. Committee formulates an outline in the form of focus questions and submits questions for review by the AACC Academy Council – 1 month suggested.
   d. AACC Academy Council reviews the proposed questions – 2 weeks.
   e. The committee formulates answers to the questions and creates a "guidance document draft" – 4-6 months suggested
   f. Guidance document draft is reviewed by the AACC Academy Council and CDC – 2-4 weeks.
   g. Committee responds to the comments from the Council. – 2-4 weeks suggested.
   h. Document is publicly posted for comments – 1 month.
   i. CDC reviews comments to ensure rigorous peer review – 2 weeks
      ▪ Additional peer or journal review may be required – 2-3 weeks if needed
   j. Committee responds to comments – 2-4 weeks suggested.
   k. Document is sent to AACC BOD for approval – 2 weeks
   l. Final draft of guidance document is "published."

7. **Distribution**
   Guidance documents will be made available for distribution on the AACC Academy web site and will be promoted through regular channels. Some guidance documents may be submitted for publication in a peer-reviewed journal (preferably an AACC journal). Exceptions to an AACC Journal may be considered when collaborating with other organizations.

Appendices:
   A. Academy Document Types
   B. Academy Guidance Document Process Flow Chart
   C. Academy Internal Review Process
   D. Academy Internal Collaboration Process
   E. Academy External Collaboration Process