

Background Information and Instructions for Developing a Statement, Practice Guideline or Other Project

Statements, practice guidelines, or other projects are sponsored by Committees of the ACMG or by the Board of Directors. Proposals from special interest groups (or individual members) should be submitted to the ACMG Office for assignment to the most appropriate ACMG Committee. All proposals are submitted to the ACMG Board of Directors for approval, and they shall adhere to the principles elaborated below.

In general, practice guidelines statements and points to consider will be drafted by a Workgroup, under the guidance of a Sponsoring Committee of the ACMG. The Workgroup:

1. Should typically be composed of 2 to 8 individuals from different institutions representing the range of expertise necessary to produce the work product. If there is more than one member of the Workgroup from the same institution, the need for their combined expertise must be justified on the proposal form. This circumstance should be rare. A significant effort should be made to include individuals from geographically diverse institutions in any given Workgroup.
2. Should be comprised of ACMG members. If a non-ACMG member is included in the Workgroup, the need for such outside expertise should be justified on the proposal; this is largely reserved for situations in which the expertise required is not found within the ACMG membership.
3. Should have a Chair or 2 co-chairs. The Chair or at least one of the co-chairs must not have any potential conflicts with the proposed project (see below).
4. At least one individual in the Workgroup must be a member of the Sponsoring Committee and serve as the committee liaison to the workgroup.

The Workgroup Chair, in consultation with the Sponsoring Committee and Committee's ACMG Staff Liaison, must complete an ACMG Proposal Form, ensuring that all information is complete and accurate. The proposal must contain an initial outline that describes and justifies the need for the project and lists the Chair or co-Chairs and the other proposed members of the Workgroup. Once the proposal and Workgroup have been approved by the Sponsoring Committee, the proposal should be submitted to the ACMG administrative offices. Each member of the Workgroup must complete an online PARTICIPATION AGREEMENT that includes a disclosure of potential conflicts. To ensure confidentiality, completed and signed participation agreements should be submitted online. Submitted proposals and participation agreements will be reviewed by the ACMG Conflict of Interest Committee.* If the proposal is approved by the Conflict of Interest Committee, it will be forwarded to the ACMG Board of Directors for review.

5. **No work should commence on a project until the proposal and all PARTICIPATION AGREEMENTS have been approved by the ACMG Board of Directors.**
6. Any significant post-approval changes in the scope of the project or the membership of the Workgroup must be submitted to the ACMG office for serial review by the Conflict of Interest Committee and the ACMG Board of Directors.

Authorship and External Review

Writing statements and guidelines takes a tremendous amount of work. Authorship is best determined at the initiation of the project, based on level of contribution. Those Workgroup members who make substantial contributions to the conceptual development of a project and/or the writing and editing of a document will receive authorship when the work product is published. The guidance, review, and support of the Sponsoring Committee will be acknowledged, but Workgroup and committee members who do not fulfill the requirements of an author will not be individually listed on the title page of the publication. Authorship for documents undergoing revision should include only those individuals making a significant contribution to the revised work product. ***With regard to External Review:*** Occasionally the Board or Sponsoring Committee may request an external review by a subject matter expert. Similarly, when outside expert reviewers have been used, they may only be cited (thanked) in the Acknowledgment section of the paper if a Participation Agreement has been completed and approved by the Board. COI committee approval should be sought as soon as the need for external review and acknowledgement is recognized.

The suggested format for the listing of authors of statements and guidelines shall be:

“ Name 1, Name 2, Name 3 (for each author) on behalf of the YY Workgroup of the American College of Medical Genetics and Genomics (name) Committee.”

The suggested format for statement and guideline titles shall be:

“XXX, A Practice Guideline/Policy Statement, etc. of the American College of Medical Genetics and Genomics (ACMG)”

Publication

Guidelines, statements and other written documents to be published in *Genetics in Medicine* will adhere to the publication policies of the journal. Specifically, publications in full must adhere to a limit of ≤4500 words and 40 references (references not included in the word limit). Authors must justify that the document is of sufficient general interest and impact to warrant inclusion as a full article. This request should be made at the time of initial board review at the latest. Additional text, figures, tables, etc. can be accommodated as online supplemental material.

Written documents that are limited in scope or incremental in content, such as guideline revisions with minimal changes, will generally be published in their entirety by *GIM*, as “online only”. The final decision on publication (“online only” vs. print) will be determined by the *GIM* editors and will be based on such factors as document size, scope, etc. All “online only” documents will be listed in the Table of Contents of, and therefore associated with, a specific issue of *GIM*. “Online only” publications will also be listed in, citable and searchable through PubMed.

***Conflict of Interest Disclosures and Review**

In April 2011, the Board of Directors of ACMG agreed to adhere to a Code of Conduct developed by a task force of the Council of Medical Specialty Societies (CMSS) regarding interactions with for-profit companies. As part of this code, practice guidelines, statements and other activities of the ACMG must be “developed through

a rigorous independent process, based on the best available scientific evidence.”¹ To adhere to this objective and ensure that guidelines and other projects of ACMG have the highest transparency possible:

1. All members of a Workgroup, authors of a guideline or statement, expert advisors, and/or outside expert reviewers must complete a PROJECT PARTICIPATION AGREEMENT that includes a disclosure of potential conflicts.
2. The Chair (or at least one co-chair) of the Workgroup must be free of potential conflicts with regard to the subject matter of the project or guideline.
3. At least a majority of the Workgroup (>50%) must be free of potential conflicts with regard to the subject matter of the project or guideline.
4. To maintain confidentiality, Participation Agreements will be submitted online to the ACMG administrative offices by each participant on the Workgroup. They will be reviewed by the Conflict of Interest Committee and approved or rejected by the ACMG Board of Directors.
5. Workgroup Members must decline offers to speak about the guideline or statement from any commercial entity that could be affected by the work product during the drafting of the document and for a period of one year following its publication. More specifically, during this period, Workgroup members cannot discuss the document, speak at a meeting at which the guideline is one of the major topics, or allow the commercial entity to state that the individual was on the panel/Workgroup that developed the document.
6. ACMG Workgroup members **cannot** be involved with a similar workgroup of another organization; nor may they accept an invitation to become involved in such an activity during the time of their involvement with an ACMG project, or for six months thereafter.
7. There are some circumstances where involvement with a for-profit company would prohibit participation of an individual on a work group. These are detailed in a separate document entitled “Conflicts that prohibit participation in an ACMG work group.”

While the CMSS Code of Conduct applies only to interactions with for-profit entities in the healthcare sector, the ACMG Board of Directors requires disclosure by all Workgroup members of any relationship with an entity (commercial or non-commercial) that may have an interest in the guideline, statement or project, whether or not it constitutes an actual conflict of interest. Such disclosures must include, but are not limited to, the following:

1. The Workgroup member is the Director or Assistant Director of a laboratory, including academic or non-profit laboratories, performing testing related to the guideline or statement.
2. The Workgroup member is a participant in a clinical trial or outcomes research, the subject of which is related to the guideline or statement, regardless of the source of financial support.
3. The Workgroup member is on an advisory board, the subject of which is related to the guideline or statement.
4. The Workgroup member is the Director of a Specialty Clinic or Center that sees patients with disorders related to the guideline or statement.

In general, disclosures concerning activities performed for non-profit entities, such as those listed above would not be considered potential conflicts that would preclude participation.

All decisions regarding conflicts will be made by the ACMG Conflict of Interest Committee on behalf of the Board of Directors.

¹ Council of Medical Specialty Societies, Code for Interaction with Companies, March 2011.