American College of Medical Genetics and Genomics

Proposal for Statement, Practice Guideline or Other Project

(PLEASE TYPE ALL INFORMATION)

DATE:	SPONSORING COMMITTEE:
SPONSORING SUB-COMMITTEE:	
COMMITTEE LIAISON (MUST ALSO BE A WORKGROUP MEMBER):	
NAME AND TOPIC OF PROJECT:	
PARTICIPATION AGREEMENT TITLE (3-4 WORDS):	
ESTIMATED DATE FOR SUBMISSION OF DRAFT DOCUMENT TO THE BOARD:	

TYPE OF PROJECT (Please check one):

☐ **New practice guideline**. *(A practice guideline is based on an accompanying systematic evidence review and addresses an important and timely topic in clinical genetics. It should be developed in accordance with the* ACMG Protocol for Evidence-Based Guideline Development** and meet criteria for publication in Genetics in Medicine *as an evidence-based guideline and inclusion in the National Guideline Clearinghouse.)*

This document will be a: ☐ Clinical practice guideline ☐ Laboratory practice guideline
This article type requires completion of the PRISMA checklist and Figure 1 to be the PRISMA Diagram

☐ **New practice resource**. *(A practice resource also addresses an important and timely topic in clinical genetics. It is informed by evidence and expert opinion, but lacks the rigor of a systematic evidence review. It is, however, expected to have a transparent reproducible methodology, be informed by existing evidence, make justifiable recommendations, and discuss its limitations.)*

This document will be a: ☐ Clinical practice resource ☐ Laboratory practice resource*
** This category can be used to cover laboratory algorithms and other documents that do not rise to the level of a laboratory guideline.*
This article type requires completion of the practice resource checklist.

☐ **New technical standard for clinical genetics laboratories.** *(Developed and maintained by ACMG's Laboratory Quality Assurance Committee, these voluntary standards establish criteria for clinical genetics laboratories to provide accurate and reliable diagnostic testing, that is consistent with current technologies and procedures. They are written through a consensus development process, by experts in the field, and rely on published data and experience.)*

☐ **New statement.** *(A statement about a timely issue that represents the opinions, beliefs, and/or best professional judgments of the College. Policy statements outline how the College intends to act in specific circumstances. Position statements discuss where the College stands on a topic or a debatable issue and are often used to describe the goals of a positioning strategy. Points to Consider statements represent an assessment of emerging issues or new technologies in practice, and are reviewed regularly for accuracy)*

*** For more information on the development of Evidence-Based Guidelines, refer to Bradley et al (2014) "American College of Medical Genetics and Genomics Protocol Manual for Evidence-Based Guidelines."*
https://www.acmg.net/docs/ACMG_Protocol_Manual_for_EB_Guidelines_FINAL.pdf

This document will be a: ☐ Points to consider ☐ Position Statement ☐ Policy Statement

☐ **Revision** of an **existing** ACMG **statement**, **practice guideline/resource, or laboratory technical standard**. *(The previous statement or practice guideline/resource will be retired when the revised document is published.)*

The revised document will be a (check one): ☐ Policy Statement ☐ Position Statement ☐ Clinical Practice Guideline ☐ Laboratory Practice Guideline ☐ Clinical Practice Resource ☐ Laboratory Practice Resource ☐ Laboratory Technical Standards

Previous Title: _____

Publication Date: _____

☐ **Addendum** to an existing ACMG **statement** or **practice guideline/resource**.

Previous Title: _____

Publication Date: _____

☐ **Retirement or Reaffirmation of a guideline or other College document.** The requesting committee should provide a rationale for this action in the space provided on page 2. No additional information or documents are required. Requesting: ☐ Retirement ☐ Reaffirmation

Document Title: _____

Publication Date: _____

☐ **Other Project (describe):**

_____

_____

☐ **Joint Statement or Practice Guideline/Resource**

This is a joint project with other organization(s): ☐ YES ☐ NO

Other Organization(s): _____

_____

NOTE: *A Joint Statement and Guideline Form must also be completed*

** http://www.acmg.net/docs/ACMG_Protocol_Manual_for_EB_Guidelines_FINAL.pdf (found on the ACMG website under Members Only, Committee Management Resources)

Publication

Authors are encouraged to consider the final publication as they develop their document, especially to familiarize themselves with the PRISMA and practice resource checklists, to ensure they understand the requirements of each article type. All queries on publication in *Genetics in Medicine (GIM)* should be directed to Katie Murphy at geneticsinmedicine@acmg.net.

Guidelines, statements and other written documents to be published in *GIM* will adhere to the publication policies of the journal. Specifically, publications in full must adhere to a limit of:

- ≤4500 words, 40 references (references not included in the word limit), and 5 display items OR
- 10 printed pages apportioned however you want
  Note: 900 words = 1 printed page, ~ 50 references = 1 printed page.

Please be aware of the following term replacements enforced by *GIM*. If not included as indicated *GIM* will edit the former term to match the latter as follows:

- "whole-genome sequencing" or WGS replaced by "genome sequencing"
- "whole-exome sequencing" or WES replaced by "exome sequencing"
- "mutation" replaced by "pathogenic variation"
- "incidental findings" replaced by "secondary findings"

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.

Description of and Justification for the Project

Please provide 1-2 paragraphs (or bullet points) describing the project. Include:

1. Key questions to be asked or answered
2. Why there is a critical need for the guideline (e.g., controversy in field, new treatments or diagnostic tools available, new technology affecting clinical practice, etc.)
3. Potential to affect change in practice, potential usefulness to improve quality of care and/or potential risk of inaction or harm with lack of this clinical guidance

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Target audience (check all that apply):

- ☐ Clinicians
- ☐ Laboratorians
- ☐ Regulatory bodies
- ☐ Educators
- ☐ Public policy makers
- ☐ Third-party payers
- ☐ Media
- ☐ General public
- ☐ Other (please list)

Workgroup:

Please list the Chair (or two co-chairs) as well as all additional Workgroup members. List their title, institution, and expertise or role in the project. Note that Workgroups will typically consist of 2-8 members. Preference should be given to ACMG members; where particular outside expertise is required, the inclusion of a non-ACMG member must be justified below. In addition, if more than one Workgroup member from the same institution is proposed, the need for the inclusion of both members must be justified. Note that the Chair or at least one of the co-chairs and at least the majority of the Workgroup (>50%) must have no potential conflicts of interest as defined in the Participation Agreement. In addition, the Workgroup Chair must be an ACMG member.

*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.*

Workgroup Members (add additional rows to the table as needed):
Each work group chair should strongly consider adding a clinical geneticist, laboratory geneticist, and genetic counselor as the focus of the document dictates. Failure to do so may delay approval of the proposal. If, due to the scope of the document, the work group chair does not believe inclusion of any one of these individuals would enhance the proposal in question, please include a justification for exclusion of these individuals within the proposal.

Name (indicate Chair)	**Title, Institution**	**Expertise/Role in Project**	**ACMG Member?**
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No

Please justify inclusion of (2) two or more individuals from a single institution and/or any non-ACMG member(s) below, if applicable

PLEASE HAVE EACH MEMBER OF THE WORKGROUP REVIEW, COMPLETE AND SIGN THE PARTICIPATION AGREEMENT AVAILABLE AT http://www.acmg.net.

Proposals will not be considered until a signed Participation Agreement is submitted for each individual listed in the table of Workgroup members.

Participation Agreement forms should be completed and submitted online. The blank form is located under the "Committees" tab on the ACMG website (www.acmg.net), as "ACMG Participation Agreements" in the pull-down menu.

After the Authoring Entity Completes this Proposal:

- The Proposal is reviewed by the Sponsoring Committee. *If approved:*
- The Proposal and necessary Participation Agreements are submitted separately to the ACMG administrative office and are reviewed by the ACMG Conflict of Interest Committee. *If approved:*
- The Proposal and the summary of Participation Agreements are reviewed by the Board of Directors. *If approved:*
- The Chair or (Co-Chairs) are notified of the approval and given a one (1)-year deadline to submit a draft to the Sponsoring Committee. The Chair or Co-Chair(s) are encouraged to work closely with the ACMG Staff and Board of Directors Committee Liaisons in order to meet deadlines and assure that content is in accordance with the Proposal.
- The Sponsoring Committee reviews the draft, provides feedback to the author(s), and the authors have three months to make their revisions for final Sponsoring Committee approval.
- Once the final document has been approved by the Sponsoring Committee, it is submitted to the Board of Directors for final review. At the same time, the paper is submitted electronically to the ACMG membership for 30-day comment and review. Comments are collected in the ACMG office.
- After the 30-day period has passed, comments (if any) are summarized and sent back by ACMG staff to the lead author(s) for incorporation into the document. The authors will incorporate comments as appropriate, using track changes, and then send the document back to the ACMG Staff Liaison, the Sponsoring Committee Chair and the designated Board Liaison. The authors must include an annotated list of all comments received and the action(s) taken on each one.
- The final paper and summary of comments with author responses are presented by the ACMG Staff Liaison and/or designated Board Liaison for final approval by the Board of Directors. *Once approved:*
- Once approved, the paper is finalized and put into official *Genetic in Medicine* format by the authors. The link to instructions to authors is: https://www.nature.com/documents/gim_new_gta.pdf. Required Author License to Publish forms can be found here: https://www.nature.com/gim/authors-and-referees/authors#author-forms
- 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 BOD.
- The paper is submitted to the ACMG Office for publication in *Genetics in Medicine.*
- The document is posted on-line, published ahead of print, on the *GIM* and ACMG website. Once the document has been published by *GIM*, it should be replaced on the ACMG website with the final version (since this one includes page numbers and all the information needed for citation).
- The Document is to be reviewed after five years to determine if it should be reaffirmed, retired, or revised. If major scientific advances have occurred, revisions may need to be made sooner.
- NOTE: In special situations, work in progress may be submitted for presentation, such as at an ACMG meeting. These situations must be cleared with the Committee Chair and designated Board Liaison, and the submission/presentation must include all the appropriate disclaimers, including that this is a

work in progress and not a Board approved guideline/policy/position. These venues are another way to seek public comment for a document under development.

- 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.