SMG 9010.3

FDA Staff Manual Guides, Volume IV – Agency Program Directives

General or Multidiscipline

Decision and Dispute Resolution

Authorship Dispute Resolution at FDA

Effective Date: 01/14/2021

1. Purpose

A strong commitment to the successful resolution of authorship disputes is necessary to protect the overall integrity of research conducted by the U.S. Food and Drug Administration's (FDA's or the agency's) scientific community. This document describes how authorship disputes should be managed throughout FDA, sets forth recommended elements to be included in authorship dispute resolution processes adopted by agency components, and establishes an agency-wide process for authorship disputes at the Office of the Commissioner (OC) level.

2. Scope and Policy

The procedures described in this document address authorship disputes arising within FDA's scientific community. For the purposes of this guide, authorship disputes are disagreements related to the provision or apportioning of credit for written materials resulting from the collaboration of two or more individuals and intended for submission to a peer-reviewed publication.[1] To avoid authorship disputes, FDA encourages discussion among collaborating researchers at the outset of any research project concerning how authorship credit will be apportioned.

[1] The policies and processes described in this SMG apply to disagreements related to the inclusion or exclusion of an author as well as disagreements related to authorship order determinations.

These procedures apply when such a dispute arises among collaborators and involves one or more members of FDA's scientific research community.[2] For the purposes of this policy, FDA's scientific research community includes government employees, fellows (including fellows managed through the Oak Ridge Institute for Science and Education (ORISE) and other non-governmental employee trainees), contractors, visiting scientists, guest workers, and other similarly situated members of FDA's internal research community.

These procedures do not address potential research misconduct or scientific disputes related to FDA regulatory decisions. Research misconduct consists of fabrication, falsification, or plagiarism associated with research, and is governed by Staff Manual Guide (SMG) 9003.1: Policy for Responding to Allegations of Research Misconduct. The policy and procedures for scientific disputes related to agency decision-making are found in SMG 9010.1: Scientific Dispute Resolution at FDA. Questions concerning which guidelines apply to a particular dispute should be directed to the Agency Intramural Research Integrity Officer (AIRIO) at AIRIO@fda.hhs.gov within the FDA Office of Scientific Integrity, Office of the Chief Scientist, Office of the Commissioner.

3. Applicable Authorship Criteria

FDA recognizes that the purpose of any set of authorship criteria is to identify factors that typically suggest that an individual's contribution to a written work merits authorship credit for that work. As such, all authorship criteria lists are best viewed as reference points rather than rules. Most fundamentally, decisions at FDA concerning authorship disputes should be guided by the facts of a particular dispute and motivated by a desire to ensure basic fairness to individuals making material contributions to written work at FDA.

Although the agency recognizes that authorship criteria may vary by discipline, agency employees and formal review panels at FDA should apply the authorship criteria set forth in the International Committee of Medical Journal Editors (ICMJE) publication "Defining the Role of Authors and Contributors" (Appendix B) when evaluating individual authorship disputes, unless component procedures specify circumstances in which additional or alternative criteria should be applied.

The ICMJE recommends that authorship be based on the following four criteria:

[2] For authorship disputes involving only one member of FDA's scientific research community and outside parties, the disputing author should contact their component Ombudsman (or other appropriate official within their component) to discuss whether modifications to component and/or agency procedures are necessary to effectively address the dispute. Officials contacted under such circumstances may consult with the Agency Intramural Research Integrity Officer (AIRIO) for assistance adapting and applying agency and agency component procedures when necessary.

- substantial contributions to the conception or design of the work; OR the acquisition, analysis, or interpretation of data for the work; and

- drafting the work OR revising the work critically for important intellectual content; and

- final approval of the version to be published; and

- agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In their description of the purpose of these criteria, the ICMJE publication notes that "the criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion two or three… all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript."[3]

4. Agency Expectations and Responsibilities

Individual agency components, such as Centers and the Office of Regulatory Affairs (hereinafter "centers" or "components"), are encouraged to develop and implement authorship dispute resolution procedures and practices that address their specific research environments and preferences. This section sets forth recommended elements that should be considered by agency components when adopting and revising their component-specific authorship dispute resolution procedures. This section also sets forth the agency's expectations for individual members of FDA's scientific community.

a. Preventing Authorship Disputes Through Communication and Documentation.

FDA encourages all researchers, whenever feasible, to expressly define and document expectations for authorship credit as part of the initiation of any research project or collaboration at FDA that is likely to result in written work within the scope of this SMG. An initial discussion among collaborating researchers at the outset of any research project concerning how authorship credit will be apportioned remains the most important bulwark against the evolution of authorship disputes. Similarly, when a research project evolves or changes in a material respect, FDA expects and encourages all the researchers involved in that project to discuss, determine, and document updated authorship expectations as soon as practical to avoid the emergence of authorship disputes in the future.

[3] See Appendix B for the ICMJE's discussion of these criteria and their underlying rationale.

If questions of authorship credit or apportionment arise at any point in a collaboration, directly discussing the issue among all collaborators is typically the appropriate first step toward attempting to resolve the dispute. The agency expects that all FDA researchers attempt in good faith to resolve authorship disagreements as they arise in a professional, fair, and collegial manner. The agency believes that this responsibility to attempt to resolve emergent authorship issues through open and frank discussion is particularly incumbent upon more established members of the FDA scientific community engaged in collaboration with more junior colleagues. Accordingly, FDA expects more established researchers in our scientific community to serve as positive examples for more junior colleagues and research partners by modeling professional, fair, and collegial efforts to resolve any such disputes in a transparent manner.

To assist and encourage FDA researchers to engage in this type of authorship discussion, determination, and documentation, agency components may consider providing specific guidelines to component researchers to encourage or require the inclusion of documented authorship expectations in research plans. A sample authorship agreement is attached to this SMG at Appendix A.

b. Providing the Voluntary Option for Assistance Resolving Disagreements.

Although the agency expects earnest and good faith efforts by all FDA researchers to resolve authorship disagreements through direct discussion among themselves whenever possible, FDA also recognizes that facilitated discussion may be useful to assist collaborators in reaching consensus on authorship apportionment. The purpose of facilitated discussion is to provide the disputing parties with access to a neutral person to help assist the parties in reaching a voluntary agreement among themselves that resolves the authorship dispute. Often, even seemingly intractable disagreements can be amicably and voluntarily resolved through the intervention of an appropriate third-party facilitator.

Accordingly, for circumstances where discussion among the collaborators by themselves is not able to resolve a dispute, FDA encourages collaborators to consider enlisting the assistance of the FDA Alternative Dispute Resolution (ADR) Program by contacting the agency's Ombudsman and Conflict Prevention and Resolution (OCPR) Staff.

Participation in ADR at FDA is strictly voluntary and not required to pursue an authorship dispute. Collaborators may elected to attempt facilitated discussion but may discontinue that process at any time and instead pursue their authorship dispute using the procedures specified by their component process and this SMG at any time.

c. Adjudicating Authorship Disputes at the Component Level.

If an authorship dispute is not resolved voluntarily by discussion, a collaborator may initiation adjudication of their dispute at the component level using the appropriate component procedure. Components will provide collaborators with a clear procedure designed to adjudicate authorship disputes at the component level. At a minimum, component procedures for such disputes will provide all collaborators with an opportunity to present the decisionmaker(s) with their views on the authorship dispute in writing. Although the agency expects and encourages individual components to tailor their procedures to their own research environments and preferences, all component procedures should identify a final decisionmaker(s) for their component. A final component decision on an authorship dispute should include a written conclusion determining how authorship should be apportioned as well as a rationale for that conclusion based on the facts and circumstances of a given dispute.

The agency encourages components to consider including a formal panel review in their adjudication procedures. If a component elects to do so, such a panel review process must be consistent with the elements and process requirements for a formal panel review described in Section 5 ("Formal Panel Review for Authorship Disputes").

d. Appealing a Final Component Decision to the Office of the Commissioner.

After a component's authorship dispute resolution procedure (including any internal review or appeals provided by the component's process) is exhausted, any party to an authorship dispute may appeal the component's final decision to the Office of Scientific Integrity within the Office of the Chief Scientist, Office of the Commissioner (OC).

To request OC review, any party to an authorship dispute should submit a written statement to AIRIO with a copy provided to the final component decisionmaker and other collaborators. This statement should request OC's review of the component's final decision and should specify the appellant's basis for disagreeing with the component's final decision, including the appellant's reason for believing that the component did not follow applicable agency or component procedure, if applicable.

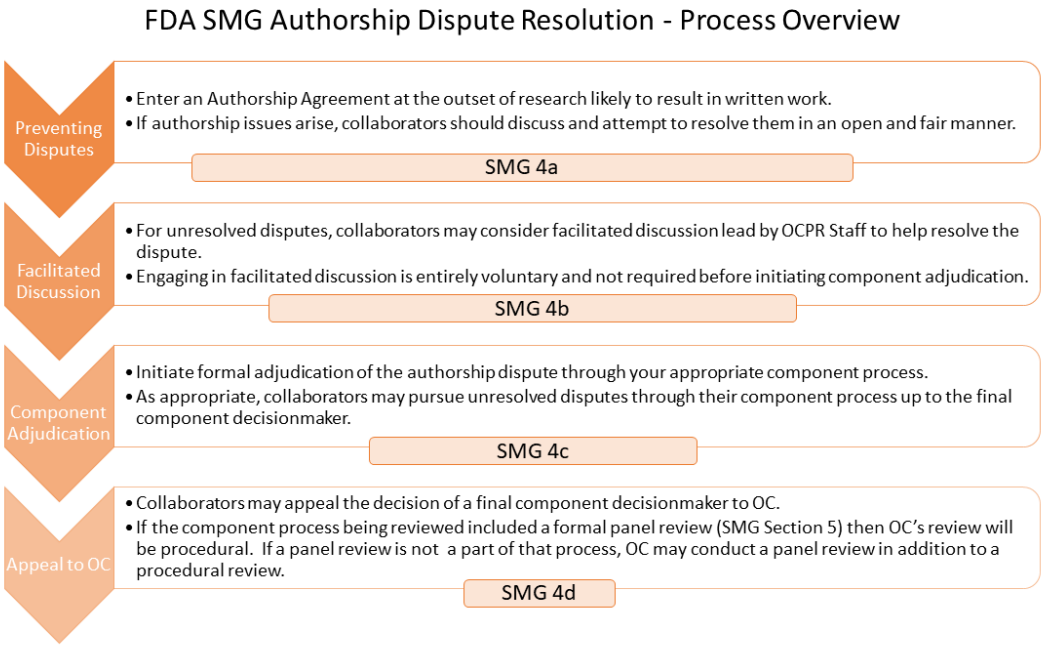
When an appeal request is made, the last component decisionmaker will coordinate with the AIRIO/OC and provide a complete copy of the record of decision for the dispute up to that point as soon as practicable (typically within less than 30 days). If needed to assist in evaluating an appeal, OC may request additional, relevant information from one or more collaborators and agency components.

If the component decision being appealed is based on a recommendation by a formal panel review, OC's review will determine whether the applicable component and agency procedures were followed. If OC's review determines that applicable procedures were followed (or that any deviations would not to have affected the final decision reached by the component), OC will provide notice of this determination, and the component's decision will represent the final decision for the agency. If OC's review determines that applicable procedures were not followed in a manner that may have affected the outcome of the dispute, OC may conduct additional fact-finding related to the dispute and may then render a final decision for the agency or remand the dispute to the agency component for further evaluation according to appropriate component and agency procedure.

In addition to the procedural review described in the preceding paragraph, if the component decision being appealed did not include a formal panel review or departs from a formal panel review's recommendation, OC may elect to conduct a formal panel review and/or issue a final decision for the agency based on a substantive review of the record. OC retains the option to remand for further action by the appealed component if new information not fully evaluated by the component is presented on appeal.

All OC decisions related to appeals of authorship disputes will be provided to the parties of the dispute as well as the final component decisionmaker being appealed.

The following flow chart provides an overview of the dispute resolution process described in this section.



5. Formal Panel Review for Authorship Disputes

Formal panels reviewing authorship disputes at either the component or Commissioner level should be composed and conducted according to the minimum requirements and guidelines outlined in this section.

a. Purpose.

The purpose of a formal panel review is to provide an objective recommendation under the applicable authorship criteria regarding the appropriate apportionment of authorship credit for a given written work based on a thorough assessment of the contributions of the collaborators.

b. Composition.

A formal review panel should include at least three unbiased, impartial members who do not have or appear to have a personal or professional interest in the outcome of the dispute. When possible, panel members may also be selected based on their knowledge related to the general scientific discipline, publication practices in a particular field, and/or research norms relevant to the dispute.

c. Access to Relevant Information.

A formal review panel should have access to all information related to the dispute necessary to reach a fair and informed decision. To this end, the panel should have access to (and disputing collaborators should provide) written statements, including any relevant attachments the parties wish to submit to the panel for consideration. The panel may directly obtain information relevant to the dispute through any reasonable and appropriate means, including conducting in-person interviews of collaborators and third-parties, requesting responses to written questions from collaborators and third-parties, and acquiring and reviewing any relevant documents.

d. Applicable Authorship Criteria.

Formal review panels at FDA should apply the authorship criteria as described in Section 3 of this SMG. Authorship disputes related to authorship order (versus authorship inclusion) will be evaluated for basic fairness under the circumstances of each case in light of the norms of publication in a particular field.

e. Rule of Decision for Inclusion versus Exclusion

When a formal review panel determines that a question of authorship inclusion (versus authorship order) could be reasonably decided in favor of either inclusion or exclusion of a particular collaborator, even following a thorough panel review of all available information and deliberation with reference to the appropriate authorship criteria, FDA policy favors erring on the side of inclusion in such close cases.

f. Record of Decision.

After evaluating all relevant information, the review panel will render a written recommendation that includes (a) the panel's conclusion concerning how the authorship dispute be resolved and (b) a detailed basis for this conclusion that discusses the material information considered by the panel.

This written recommendation and all the information submitted to or considered by the panel should be collected and retained as part of the record of decision. If a component's final decision departs from the recommendation of a formal panel review conducted at the component level, that decisionmaker will include in their decision an explanation for such a departure.

Agency components may house these documents according to their record-retention procedures and/or may transfer the complete record of decision to the AIRIO after a final decision is made.

6. Cross-Component Disputes

If an authorship dispute arises involving parties housed within different agency components, disputants are encouraged to discuss and agree in writing on the component's procedure they would prefer to govern the resolution of their dispute. If the disputing parties are unable to come to an agreement, their immediate supervisors and/or other appropriate manager(s) in their supervisory chain should discuss the matter and submit a written request with their rationale to the AIRIO, recommending the component's authorship dispute policy that seems most likely to provide a fair avenue to resolve the cross-component dispute. If no agreement can be reached on a recommendation, then the involved supervisors and other appropriate managers should notify the AIRIO, and the AIRIO will decide which procedure or combination of procedures is most appropriate.

7. Effective Date

The effective date of this guide is January 14, 2021.

8. Document History – SMG 9010.3, "Authorship Dispute Resolution at FDA."

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	01/13/2021	N/A	OC/OCS/OSI	Denise Hinton, Chief Scientist, Office of the Chief Scientist

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Appendix A: Sample Authorship Agreement

At the outset of any research project likely to result in written work within the scope of this SMG, all collaborators at FDA are encouraged to adopt authorship agreements that expressly define the roles of each collaborator and the authorship credit they expect to receive for their individual contributions, if any, as much as is feasible at the outset of a research project. This sample authorship agreement may serve as a useful starting-point for documenting expectations related to authorship allocation.

By entering this agreement, all collaborators agree that authorship allocation for publishable materials resulting from this collaboration will be allocated according to the following order, based on the expected contributions of each collaborator as described below. The collaborators further agree that the authorship order should be updated should an individual's responsibilities substantially change or should an individual fail to perform their role as agreed and described below.

Barring such a change in responsibilities, the collaborators agree and expect that authorship will be allocated as follows:

Research project name (tentative): _____

List the names of all collaborators on this project (with specific individual pages to be attached for each of these collaborators) and their anticipated authorship order and/or attribution (if known at this time):

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Each collaborator listed on the research project should fill out and attach a copy of this page to the overall collaboration agreement.

Individual collaborator name (print):

_____

Anticipated areas of contribution with reference to the ICMJE authorship criteria (SMG Appendix B):

[ ] substantial contributions to the conception or design of the work; OR the acquisition, analysis, or interpretation of data for the work

[ ] drafting the work; OR revising the work critically for important intellectual content

[ ] final approval of the version to be published

[ ] agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Generally, individuals contributing in all four of the above categories are entitled to authorship credit. Please refer to the ICMJE authorship criteria and FDA's Authorship Dispute Resolution SMG.

Specific description of the project-specific work to be performed by this collaborator:

_____
_____
_____
_____
_____
_____
_____

Expected authorship order and/or attribution(s) (e.g. first, second, third, senior, corresponding, acknowledgement, etc.) based on these responsibilities at this time:

_____

Collaborator (signature): _____ Date: _____

Appendix B: ICMJE Authorship Criteria

http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html