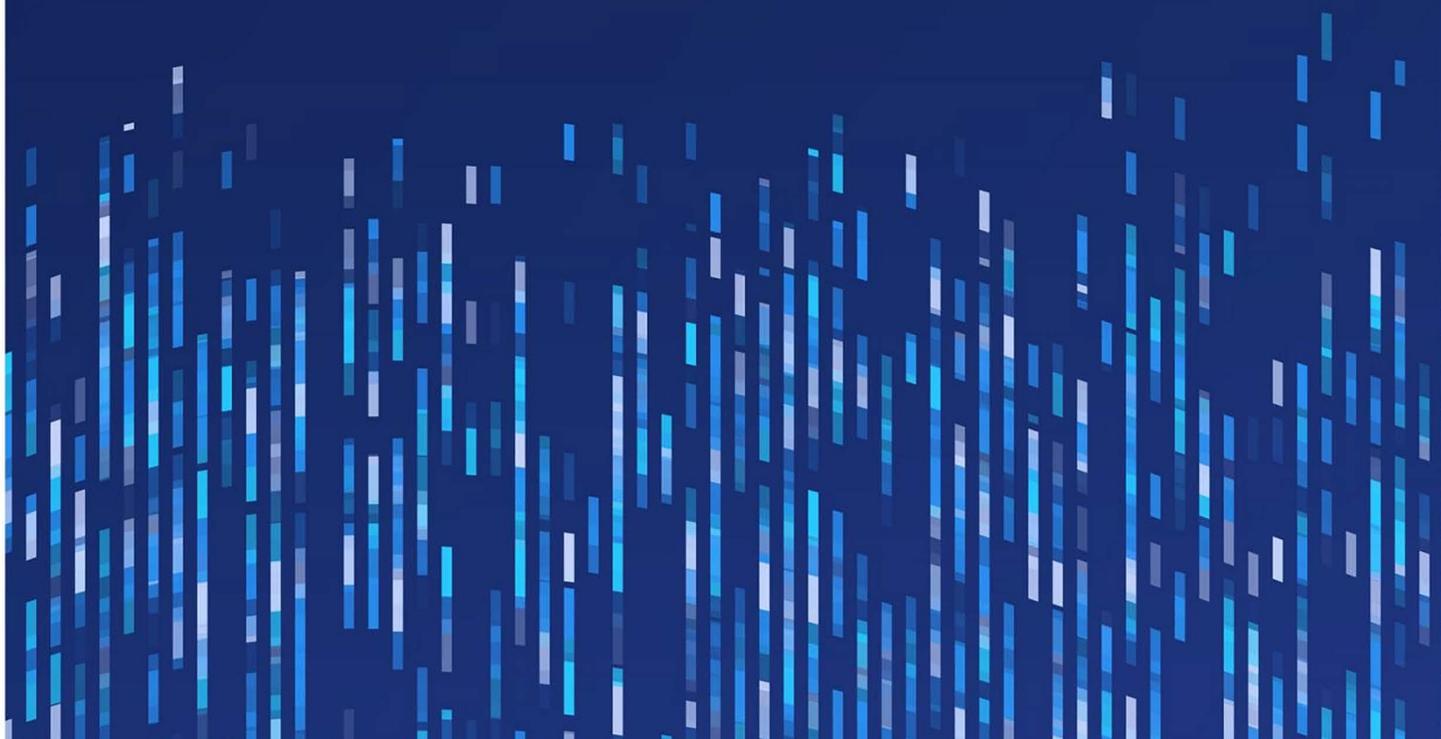


Harmonization of Financial Disclosure Reporting in Biomedical Journals: A Shared Responsibility

RECOMMENDATIONS FROM THE
WORKING GROUPS ON HARMONIZATION

DECEMBER 2021



Executive Summary

Safeguarding public trust in biomedical research requires consistency across biomedical journals and the research enterprise as a whole in the reporting of financial interests and professional relationships. While the research community has made meaningful strides toward a more unified understanding of these issues, many organizations still have similar but distinct disclosure and reporting policies that may be implemented inconsistently. Even among biomedical journals, inconsistent disclosure requirements makes it more challenging for authors to report accurately and for readers and audiences to understand the significance of disclosure reports.

The scientific and medical communities share a responsibility for the integrity of biomedical research as well as a commitment to fostering transparency and maintain public trust. Recognizing this shared responsibility, a group of organizations from across the biomedical research enterprise came together to consider whether a path could be found to harmonize financial disclosure standards, principally in connection with journal authorship. A symposium hosted by the Association of American Medical Colleges (AAMC), American Society of Clinical Oncology (ASCO), Council of Medical Specialty Societies (CMSS), JAMA, and Memorial Sloan Kettering Cancer Center (collectively the Host Organizations) in February 2019 yielded a strong consensus view that harmonized disclosure was a worthy goal and would require collaboration among multiple stakeholders. The symposium included representatives from journals, academic societies, academic medical centers, government, healthcare associations, foundations, industry, patient advocacy organizations, public representatives, and others. Following the symposium, three working groups held multiple conference calls over a six-month period to develop the Harmonized Disclosure Framework (HDF) described in this report.

A draft report was made available for public comment and review by Symposium and Working Group participants. The Host Organizations and Working Group Co-Chairs reviewed and incorporated feedback from over 50 comments from a wide range of stakeholders.

The HDF calls for manuscript authors to disclose *all financial interests and professional relationships* related to medicine, healthcare, research and life sciences, broadly defined, that existed at any point within the immediately preceding 24 months prior to the time a work is accepted for publication. Within this “comprehensive disclosure,” authors should designate which of these financial interests and professional relationships are “relevant” to the purpose of the disclosure. Relevant means directly related to the topic and subject matter of an article, and may include relationships with for-profit or not-for-profit entities. In addition to the comprehensive disclosure, authors should also disclose any and all direct sources of funding for the research presented, from the initial conception and planning of the research to the present, regardless of the type of funder. The decision to require comprehensive disclosure with a relevance designation was intended to minimize subjectivity, allowing readers to make their own judgment as to what disclosure information is pertinent to their understanding of the work. Further, the 24 month disclosure period represents a time period that yields a meaningful disclosure while presenting a manageable amount of information for journals, authors, and readers.

Under the HDF, authors retain ultimate responsibility for the complete and accurate disclosure of financial interests and professional relationships and should be given opportunities to correct their disclosures both before and after publication. The HDF does not prescribe a new enforcement mechanism for the failure to submit a complete and accurate disclosure. If concerns are raised about the completeness or accuracy of an author’s disclosure, journals should follow established standards and procedures set forth by key stakeholder organizations such as the International Committee of Medical Journal Editors (ICMJE) and the Committee on Publication Ethics (COPE) concerning corrections, errata, publication of statements of concern, retractions, and formal apologies for failure to disclose.

Harmonization of Financial Disclosure Reporting in Biomedical Journals: A Shared Responsibility

The HDF was informed by the experiences and expertise of the members of the Working Groups on Harmonization, and a primary goal for the Working Groups was to ensure the HDF could be easily updated to reflect the current research environment and align with stakeholders' disclosure practices and policies as needed. Journals are encouraged to adopt and implement the HDF as soon as it is feasible to do so in view of their own operations and resources. In addition, other stakeholder organizations across the biomedical research, education, and professional community are encouraged to adopt the HDF in order to promote consistent, transparent disclosure and management of author and faculty financial interests and professional relationships, and to help guide specialty society clinical practice guideline development.

The harmonization of disclosures across biomedical journals is but one piece of parallel and critical disclosure harmonization efforts. Throughout this initiative, the engagement of the academic, society, accreditation, and funder stakeholders not only provided meaningful input in the harmonization disclosure framework development process, but also began important conversations about how this framework could be implemented across the entirety of the research ecosystem. Opportunities for broader implementation are discussed in the report.

Contributors

The Harmonization Disclosure Framework was developed by members of the Working Groups on Harmonization, and this report was developed by the Working Group co-chairs and the host organization representatives based on the consensus achieved during working group deliberations. While all contributors had an opportunity to comment on the draft report, the list of contributors does not imply individual or organizational endorsement of each recommendation. The list below includes the individuals who contributed to the working groups and this report, and indicates the organization with which they were affiliated at the time of the work. Individuals no longer with the same organization or institution at the time of publication are marked with an asterix (*).

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The organizations coordinating the initiative “Harmonization of Financial Disclosure in Biomedical Journals” are the **Association of American Medical Colleges, American Society of Clinical Oncology, Council of Medical Specialty Societies, JAMA, and Memorial Sloan Kettering Cancer Center.**

These Host Organizations appreciate the dedication and expertise of the members of the Working Groups on Harmonization and would especially like to thank the co-chairs of each working group for their work. Throughout the initiative, all working groups received substantive input, logistic support, and ongoing guidance from representatives from these five organizations, as co-chairs, designated working group liaisons, and working group activity coordinators.

The Host Organizations would like to specifically note the substantial contributions and insight provided by Pamela Miller, who co-chaired the Working Group on Uniform Disclosure Criteria and Process. Pam’s work at *The New England Journal of Medicine* spanned 20 years and left a lasting impact on the biomedical research community, especially in the areas of disclosure and conflict of interest. Before Pam passed away on April 29, 2020, she was instrumental in the development and products of this initiative.

Section I. Relevancy of Financial Interests

Comprehensive Disclosure under the Harmonized Disclosure Framework (HDF)

Transparency and consistency in the reporting of authors' financial interests and professional relationships to biomedical journals serves as a primary foundation of the HDF. In order to ensure the complete and accurate reporting of those interests and relationships, authors should submit a "comprehensive disclosure"—the disclosure of all financial interests and professional relationships related to medicine, health care, research, and the life sciences which existed at any point within the 24 months prior to acceptance of the manuscript, and regardless of whether those interests and relationships are directly related to the article for which the information is being provided.

Assuming the information that is disclosed is up to date and reported accurately and honestly, this approach would help to provide more transparency with respect to an author's financial interests and professional relationships, decrease the likelihood that the interests and relationships relevant to the article are not disclosed, and mitigate the subjectivity related to an individual author's determination of whether specific interests and relationships should be reported. Comprehensive disclosure builds and maintains public trust by allowing readers, rather than authors, to determine which disclosures are important to the interpretation of the article. As an added benefit, a comprehensive disclosure would increase the likelihood that an author's disclosures in connection with other professional activities would be seen as providing different or new information.

Recommendations - Comprehensive Disclosure of Financial Interests and Professional Relationships

- Authors should be required to disclose all financial interests and professional relationships related to medicine, healthcare, research and the life sciences, and existed at any point in the 24 months prior to acceptance of the manuscript (i.e., comprehensive disclosure). This also includes the complete disclosure of relationships with and interests in organizations or companies whose business includes: research and development, production, marketing, sale, or distribution of healthcare/life sciences products or services (including insurers, technology companies, organizations with healthcare research products or services).
- Authors ordinarily do not report their relationships with organizations that provide clinical services directly to patients or organizations whose primary mission is to educate healthcare professionals (e.g., employment by academic medical centers). If an author has a proprietary interest in such institution(s) (e.g., equity, private partnership involving entities providing clinical services), those relationships should be reported under the HDF.

Designation of Relevant Financial Interests and Professional Relationships Directly Related to the Article

In addition to requiring the comprehensive disclosure of financial interests and professional relationships authors should also designate which, if any, of the reported interests and relationships they consider relevant (i.e., directly related) to the subject matter of the article. Under this disclosure framework, *the burden falls on the author to make the relevancy designation* because authors are the most knowledgeable about the actual and perceived relationship between the subject matter of the article and their disclosures. Journal editors are unlikely to have the requisite knowledge to determine which disclosures are relevant.

Knowing which of the disclosed interests and relationships the author considers relevant – meaning directly related to the topic and subject matter of the article and includes any relationship with for-profit

and not-for profit entities – will assist readers in assessing and interpreting the article. Furthermore, adopting a comprehensive disclosure model with a designation of relevance serves as an important “check” on the author’s determination of which interests and relationships are relevant. All of an author’s potentially related interests and relationships will be disclosed and available to journals and readers.

Recommendations - Designation of Relevant Financial Interests and Professional Relationships

- Authors should identify a subset of the relationships and interests in the comprehensive disclosure that they deem *relevant* to the subject of the manuscript. Under the HDF this means the identification of financial interests and professional relationships (current and anticipated) that are directly related to the subject matter or content of the article, including relationships with for-profit and not-for profit entities.
- To guide authors in making relevance designations, journals could consider the Public Health Service (PHS) regulatory definition of *financial conflict of interest* (“a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research”),¹ and the updated ICMJE Disclosure Form’s description of *related*: “any relation with for-profit or not-for-profit third parties whose financial interests may be affected by the content of the manuscript.”²
- Journals should also consider supplementing definitions of relevant with questions such as:
 - Does the relationship affect the author’s individual financial interest (e.g., could the author’s financial interests increase or decrease depending on their work/research)?
 - Could the financial interests of a commercial entity with which the author has an interest or relationship be affected (positively or negatively) by the author’s work?
 - Does the work report on research that uses a product, technology or service that is owned, manufactured, or sold by the entity in which the author has an interest or relationship? If so, does the work evaluate the product, technology or service?

Potential Challenges and Objections

The recommendations for comprehensive disclosure with relevance designations would help to ensure consistency, improve transparency around the author’s financial interests and professional relationships disclosed to biomedical journals, as well as serve as the basis for stakeholders to harmonize disclosures for other scientific activities. Potential challenges with this approach were discussed by the Working Groups and should be noted. First, if authors’ disclose large numbers of financial interests and professional relationships, it may be difficult for readers to separate the true disclosure ‘signal’ from potential ‘noise.’ Nevertheless, the requirement that authors designate a subset of disclosures they deem relevant should help readers identify important interests, relationships and potential conflicts of interest. Second, the recommended disclosure model could increase the administrative burden for journals in the collection, processing, and publication of the additional disclosure information included in biomedical articles. However, with the technological capabilities of journal submission systems, it is likely that a proposed financial disclosure reporting mechanism would address these concerns.

¹ Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought, 42 C.F.R. 50, Subpart F and Responsible Prospective Contractors, 45 C.F.R. Part 94 (2011).

² International Committee of Medical Journal Editors, *ICMJE Disclosure Form*, <http://www.icmje.org/conflicts-of-interest/> (last visited July 13, 2021).

Section II. Uniform Disclosure Criteria and Process

In addition to the recommendations for comprehensive disclosure with relevancy designations, the HDF is based on biomedical journals' applying a common set of criteria by which authors disclose their financial interests and professional relationships. Uniform instructions and expectations for author disclosure would remove variation that may impact readers' ability to objectively interpret research findings. When developing specific definitions and terminology for the HDF, the feasibility, scalability, and impact of the recommendations on authors, journals, and other stakeholders was considered.

Disclosure Period for Financial Interests and Professional Relationships of the Author

A threshold instruction from journals to authors concerns the period of time during which the reported financial interests and professional relationships existed: *the disclosure period*. A two-year (24 month) disclosure period is attainable under the HDF and believed to be a reasonable compromise for journals and organizations whose disclosure periods may differ. Notably, this recommendation was developed with careful attention to whether it could be operationalized and sustained within the comprehensive disclosure (with designations for relevancy) process. There was also significant interest in harmonizing the HDF's disclosure period with standards currently used by journals and other stakeholders that have reporting requirements.

There are varying benefits associated with different disclosure periods, whether it is a period of twelve months, twenty-four, thirty-six, or longer. Ultimately, what is most meaningful and relevant are those financial interests and professional relationships that exist at the time the research results are shared or existed in the immediate time period prior. Other than direct funding or support for the research being reported, relationships that existed three, four, or more years prior to the acceptance of the publication but had been concluded more than two years prior to publication acceptance, would not seem to provide or add meaningful information or context to readers' understanding of authors' relationships in the context of the submitted work.

Recommendations – Disclosure Period for Financial Interests and Professional Relationships

- Under the comprehensive disclosure recommendation, authors should first disclose *all current or anticipated* individual financial interests and professional relationships related to medicine, health care, research, and the life sciences that existed at any point *within the two years* (24 months) prior to acceptance of the manuscript.
- Second, within the comprehensive disclosure, authors should designate which of the disclosed financial interests and professional relationships are relevant (i.e. directly related) to the manuscript.
- Finally, separate from the comprehensive disclosure process, authors should disclose *any and all* direct sources of funding at any time from the *initial conception and planning of the research to the present*, regardless of the type of funder (e.g., for-profit, not-for profit, government).

To allow the capture of additional relevant financial interests and professional relationships during the disclosure timeframe, authors should be given the opportunity to update their disclosure information *after* the date of acceptance of the manuscript but *before* publication. Corrections should also be permitted after publication and if a correction is made, journals should publish a corrective notice with the author's explanation or expression of regret (for additional information on corrective actions, see *Section III. Principles of Accountability*).

Uniform Disclosure Criteria

Other disclosure criteria concern the specific nature of the financial interests and professional relationships that should be disclosed within the author's comprehensive disclosure. The core concepts that serve as the basis for the HDF were based on several existing resources, including the information and standards currently used by biomedical journals such as the revisions to the ICMJE Disclosure Form as well as the four financial interest disclosure categories developed by the *MedBiquitous Financial Interest Working Group*. The MedBiquitous working group, which consisted of a diverse group of experts in the scientific, academic, medicine, and biomedical journal community, convened from 2014-2016 to develop nationally agreed upon data specifications for financial interest and disclosure data.³ The disclosure categories included in the HDF are as follows: 1) Professional Services; 2) Financial Stake; 3) Intellectual Property; and 4) Financial Support.

Recommendations – Disclosure Criteria (*See Appendix, Sample Disclosure Criteria and Related Information*)

- The required information regarding a disclosed financial interest and/or professional relationship should identify and categorize the interest or relationship and include specific information about the disclosed interest or relationship. The information should include the name of the entity and a description or categorization of the nature of the relationship only. Under the HDF this should not include additional details about each interest, such as the monetary value of the financial interest.

The decision to exclude the monetary value (i.e., dollar amount) of the author's financial interest or and/or professional relationship from the disclosure was made in part to maintain consistency with the long-standing approach of journals and other stakeholder organizations that do not require this information. Consideration was also given to the difficulties associated with reaching consensus on a specific monetary threshold as well as the potential challenges related to a reader's meaningful interpretation of this information in the context of the author's disclosed financial interest and/or professional relationship.

Relationship Categories and Related Information

- **Professional Services** [*employment (e.g., secondary or ancillary employment outside of an individual's primary affiliation); fiduciary role; and independent contractor*] Disclosure instructions or guidance related to the Professional Services category should include consulting, speaking, speakers bureaus, advisory boards, and comparable activities.
- **Financial Stake** [*stock; stock options; other securities; other business ownership*] Disclosure instructions or guidance related to the Financial Stake category should emphasize that equity interests, including founders' shares and equity options in start-up companies, even if the value is nominal or unknown, must be disclosed as a financial interest under this category.
- **Intellectual Property (IP)** [*patent or published patent application and copyright, royalties, other licensed IP*] Disclosure instructions or guidance related to the IP category should stipulate that patents, licenses, and similar financial interests must be disclosed even if they are not yet paying royalties.

³ MedBiquitous, *Financial Interest and Disclosure Working Group*, <https://medbiq.org/financialinterest> (last visited July 13, 2021).

▪ **Financial Support** [*gift; grant/contract; travel; meals*]

- All sources of individual author support and funding for research should be disclosed in the Financial Support category.

In cases where research funding comes through the author's institution of employment and the author is carrying out the funded research as part of his/her institutional responsibilities and not personally financially benefitting from the research support to the institution, there may be some confusion related to the disclosure of such support in the context of an individual financial interest disclosure.

However, research support from entities related to medicine, health care, research, and the life sciences could be relevant to an article and/or inform readers of potential biases, even when such sources are not directly supporting the research that is the subject of the submitted work and/or do not involve specific individual financial interests and professional relationships of the author(s).

Any and all direct sources of funding for the research in the submitted work should continue to be separately disclosed in the context of the manuscript.

- Travel and meals should be disclosed as a separate entry in the Financial Support category *only when* they represent distinct transactions or relationships not already disclosed in another financial interest category (i.e., solely a travel payment or reimbursement with no associated professional services or disclosure).

The disclosure process under the HDF captures financial interests and professional relationships with companies, not dollar amounts, and without the need to track each payment, the overall relationship that would result in a sponsored or reimbursed travel disclosure would generally already be captured in the Professional Services category. Although the Centers for Medicare and Medicaid Services' (CMS) Open Payments system captures this information separately, the Working Groups on Harmonization do not recommend such an approach under the HDF.

Disclosure of "Other" Financial Interests and Professional Relationships

The disclosure criteria outlined above adequately captures the types of financial interests and professional relationships critical for stakeholders to be aware of and therefore, the HDF does not require the inclusion of additional financial interest and/or professional relationship categories.

A separate open-ended question would allow for the capture of *other* additional financial interests and professional relationships relevant to the submitted work which should include but not be limited to:

- 1) Financial interests and professional relationships held by an author's immediate family member(s) if relevant to the submitted work;
- 2) Any other financial interests and professional relationships relevant to the submitted work and not already disclosed.

Recommendations – “Other” Financial Interests and Professional Relationships

- **Financial Interests and Professional Relationships of Immediate Family Members** - The financial interests and professional relationships of an author’s immediate family member should be disclosed by the author *only when* such interests or relationships are relevant (i.e., directly related) to the article and *should not* be disclosed in the context of a “comprehensive disclosure.” It is sufficient for the author to disclose the immediate family member’s relevant relationship in response to the “other interests” question. Journals should adopt the Public Health Service definition of “Immediate Family Member” which only includes spouse and dependent children.⁴
- **Institutional Interests** - The recommendation that authors disclose only individual interests, not those held by their institutions, is made in part because it is *not feasible* for each author to know all potentially related institutional interests. However, if an author has specific knowledge of any financial interest or professional relationship that is directly related to the submitted work (whether held by an individual or institutional) and the author believes disclosure of that interest would be important for readers or editors, this information should be disclosed in the “other interests” question.

⁴ Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought and Responsible Prospective Contractors, *See* Note 1.

Section III. Principles of Accountability

Author Responsibility for Complete and Accurate Reporting

Under the HDF, and consistent with all current processes for disclosing to journals, disclosure is the author's responsibility. Biomedical journals should expect authors to provide a complete and accurate reporting of financial interests and professional relationships, helping to proactively foster and preserve public trust in the biomedical research enterprise and enabling readers to make individual determinations about whether authors' interests are pertinent to the interpretation of the article. Author disclosure requirements should be based on a fundamental presumption of trust and integrity and not designed around "bad actors," those individuals who may not embrace transparency or purposefully omit or falsify data. These principles of responsibility and trust underlie the HDF. The goal of a harmonized disclosure framework is to ensure that expectations and definitions provide sufficient clarity to authors regarding what should or must be disclosed. Those who purposefully mislead editors or readers should be held accountable for their actions.

The ICMJE⁵ and COPE⁶ provide guidance to help interested parties identify steps that should be taken to meaningfully address publication and editorial issues whether from honest error or deception or intentional manipulation of data in a submitted or published work. These resources are also useful to journals and stakeholders when addressing issues with author disclosure. Journals and stakeholders should be encouraged to incorporate the HDF's recommendations into their policies and processes, along with relevant guidance from organizations such as ICMJE, COPE, and clearly communicate these policies and processes to authors and reviewers.

Recommendations – Author Responsibility for Complete and Accurate Reporting

- Every author plays an important role in the preservation of public trust and confidence in the biomedical research enterprise and has a primary responsibility for the complete and accurate reporting of financial interests and professional relationships under the HDF.
- Potential allegations expressing concern regarding disclosure practice by author(s) related to the submitted or published work should *not* be labeled as "research misconduct" as defined by the Department of Health and Human Services' Office of Research Integrity.⁷ While such allegations should prompt further review by appropriate parties, disclosure is a matter between the author and the journal, separate from the conduct of the research itself.
- Authors should be provided with the opportunity to clarify or correct disclosure errors or omissions *after acceptance* of the article but *before publication*. Corrections should also be permitted *after publication* and if a correction is made, journals should publish a corrective notice with the author's explanation or expression of regret.
- The information that is publicly available in the CMS Open Payments system may be a useful comparator in some cases but should not be considered a comprehensive source of information about what should be disclosed by authors. Physicians have limited control over the information reported about them by manufacturers and published on the CMS Open Payments website. Given the requirements of the Open Payments program are set forth in statute (Section 6002 of the Patient

⁵ International Committee of Medical Journal Editors, *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*, <http://www.icmje.org/icmje-recommendations.pdf> (Last visited July 13, 2021).

⁶ Committee on Publication Ethics, *Best Practice and Guidance*, <https://publicationethics.org/guidance/> (last visited July 13, 2021).

⁷ Department of Health and Human Services, Office of Research Integrity, *Definition of Research Misconduct*, <https://ori.hhs.gov/definition-research-misconduct> (last visited July 13, 2021).

Protection and Affordable Care Act), there are limitations on the changes CMS can make without statutory authority. Further, Open Payments is a U.S.-only reporting system and only includes information about physicians and a limited number of other healthcare providers. Most basic scientists or other Ph.D. or non-M.D. authors will not be included in the database. Journals and key stakeholders (e.g., academic institutions, professional societies) should view Open Payments as *complementary* to the HDF. When feasible, they should encourage authors to utilize the educational resources and tools provided by CMS and other organizations to help facilitate the Open Payments review, dispute, and data correction process. Because the sources of information and criteria differ between Open Payments and the HDF, any discordance between author disclosure under the HDF and the information published on the Open Payments website should not be presumed to be an author's error or intentional omission.

- Editors also carry important responsibilities such as the management of potential or perceived conflicts of interest raised by their own financial interests and professional relationships related to the article under review. Editors and senior journal staff should furnish their comprehensive disclosure according to the HDF and should also follow the policies and guidelines outlined by the ICMJE, COPE, and other organizations to make appropriate editorial judgements (e.g., recusal, publication of disclosure statements).

Corrective Actions – Consequences for Failure to Completely and Accurately Disclose

There may be circumstances where corrective actions are needed to rectify issues such as honest errors, misinterpretations, or purposeful misrepresentation of financial interests and professional relationships. While the HDF does not provide specific recommendations on author discipline, journals should refer to existing rules and conventions set forth in medical publishing and the continuing medical education community to make a determination on whether an error was intentional and the necessary steps for corrective action.

Recommendations – Consequences for Failing to Completely and Accurately Disclose

- If corrective action is necessary, journals should follow established standards and procedures set forth by key stakeholder organizations such as the ICMJE and COPE concerning corrections, errata, publication of statements of concern, retractions, and formal apologies for failure to disclose.
- Egregious cases *may* require journals to communicate the matter to an author's employer or home institution for review and potential corrective action.
- Corrective actions in other contexts, such as continuing professional education, should follow relevant accrediting body standards and practices.

Section IV. Adoption and Implementation of the Harmonized Disclosure Framework

Adoption of the HDF and Coordinated Communication across Key Stakeholders

Harmonizing disclosure requirements is a challenging undertaking. For the HDF to be successful, there is a need for coordinated communication, shared responsibility, and wide adoption across domestic and international journals. Consistency and trust would be further enhanced if the HDF was adopted by other organizational entities that require individual reporting of financial interests and professional relationships with companies. These other stakeholders may include academic institutions, professional societies, scientific congresses, continuing medical education community, healthcare providers, federal funding agencies, governmental and non-governmental advisory panels, and grant-making organizations. Use of the HDF by these stakeholders would promote consistency and ease administrative burden for authors, faculty, and professionals.

Recommendations – Adoption of the HDF and Coordinated Stakeholder Communication

- Wherever possible, the ICMJE member journals should incorporate the recommendations and principles of the HDF into the updated ICMJE Disclosure Form.⁸ Adoption of the key aspects of the HDF could help build on the ICMJE’s efforts to improve and streamline the disclosure process (see *Section V. Harmonization with ICMJE’s Disclosure Form*)
- Large-scale publishers and journal hosting platforms are encouraged to integrate the HDF into their policies as soon as it is feasible to do so.
- Full author disclosure, including the comprehensive set of financial interests and professional relationship information designated by the author as relevant, should be accessible to all readers of the article.
- While the HDF’s recommendations are primarily intended for journals, the Harmonization Initiative received substantial feedback that other interested stakeholders would benefit from incorporation of relevant aspects of the HDF into their organization’s disclosure policies and processes. Representatives from many of these organizations participated in all aspects of the Harmonization Initiative and provided valuable input and insight throughout these efforts.
Continuing Medical Education Community: The ACCME, is a leader in the continuing medical education community and ACCME representatives were engaged throughout the Harmonization Initiative. The organization completed a process to amend its *Standards for Integrity and Independence in Continuing Medical Education*⁹ and many of those changes are consistent with the recommendations in this report. The ACCME is encouraged to incorporate the basic elements of the HDF in its Standards.
- ***Government Departments and Agencies:*** U.S. agencies and departments should refer to the HDF’s recommendations to inform new or existing policy, regulations, or government activities (e.g., White House Office of Science and Technology Policy’s current efforts to consider streamlining conflict of interest reporting requirements across government agencies).¹⁰

⁸ ICMJE Disclosure Form, *See Note 2.*

⁹ Graham McMahon, *Changes to the Standards for Integrity and Independence in Continuing Medical Education*, April 15, 2021, JAMA, <https://jamanetwork.com/journals/jama/fullarticle/2778925>. Also see, Accreditation Council for Continuing Medical Education, *Standards for Integrity and Independence in Accredited Continuing Education*, December 10, 2020, <https://www.accme.org/standards-resources> (last visited, July 13, 2021).

¹⁰ Office of Science and Technology Policy, *Request for Information on the American Research Environment*, 84 Fed. Reg. 65194 (November 26, 2019).

- **Research Funding Agencies:** The National Institutes of Health, Food and Drug Administration, and National Science Foundation should accept disclosure reports that utilize the HDF.
- **Academic Institutions:** To help support implementation of the HDF, research institutions should be encouraged to incorporate key aspects of the HDF, whether through inclusion in institutional conflict of interest policies or processes or through educational opportunities for faculty and staff. Federal and state regulations may require academic institutions to collect information in a different way than what has been recommended under the HDF.

Considerations for Implementation of the HDF

Implicit in the design of the HDF is the flexibility for journals and other interested stakeholders to make implementation decisions that fit their organizational needs. The HDF has also been designed to permit easy updates or modifications as the disclosure landscape is influenced by new regulations, policies, or disclosure standards.

Recommendations - Considerations for Implementation of the HDF

- Journals and organizations are encouraged to implement the HDF with minimum modification or customization to ensure the recommendations are applied consistently across stakeholders that adopt the HDF. This may require transitioning away from prior disclosure requirements. It is recognized that in some cases, it may be necessary for an organization to require supplemental disclosure of information for specific professional activities or to help manage potential conflicts of interest.
- The ICMJE, as part its efforts to revise its disclosure collection process and form, announced several updates to their disclosure policies in a 2020 Editorial,¹¹ including the acceptance of disclosures from web-based repositories with criteria consistent with the ICMJE standards such as the AAMC's Convey Global Disclosure System,¹² and encouraged the development of other repositories that meet those qualifications. The decision to accept disclosures from the ICMJE qualified web-based systems will help minimize unintentional author disclosure errors or omissions in addition to accommodating regional, linguistic, and regulatory needs. Organizations should have the flexibility to implement the HDF using technology that is appropriate for their organization.
- Journals, professional societies, and other interested stakeholders should implement the HDF within a reasonable amount of time to ensure consistent implementation with other stakeholders across the biomedical research community. This timeframe should be based on the organization's operational needs, resources, and bandwidth.

¹¹ Darren B. Taichman et. al. *A Disclosure Form for Work Submitted to Medical Journals - A Proposal from the International Committee of Medical Journal Editors*, February 13, 2020, New England Journal of Medicine. https://www.nejm.org/doi/full/10.1056/NEJMe2000647#article_references (Last visited July 13, 2021).

¹² "Authors can also complete the new ICMJE disclosure on convey.aamc.org at no charge and save and download a copy of the completed form to send to a journal requesting the disclosure." http://www.icmje.org/news-and-editorials/updated_disclosure_form_2021.html.

Section V. Harmonization with ICMJE's Disclosure Form

The Harmonization Initiative has greatly benefited from the input and guidance of the representatives from the ICMJE journals¹³ who have served as co-chairs and members of the Working Groups on Harmonization, as well as participants at the *Symposium on Harmonizing Financial Disclosures in Biomedical Journals*.¹⁴ As detailed throughout the report, the HDF was also developed with consideration for existing resources, including the ICMJE's *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals* and the Committee's recent efforts to revise the *ICMJE Form for the Disclosure of Potential Conflicts of Interest* for work submitted to medical journals, now finalized as the *ICMJE Disclosure Form*.

In February 2021, the ICMJE released revisions to its disclosure form that may be adopted by journals that follow the group's recommendations. While the ICMJE made several modifications that brought it closely in line with certain aspects of the HDF, this process still diverges from the recommendations of the Working Groups on Harmonization. As discussed during the harmonization symposium and in subsequent working group deliberations, the inconsistent application of the ICMJE Disclosure Form across journals and the form's reliance on author decision making about which interests were relevant and thus needed to be disclosed, were discussed as contributors to inconsistent and incomplete disclosures.

While many biomedical journals follow the ICMJE's recommendations and author Disclosure Form, the ICMJE does not require, monitor, or enforce its use,¹⁵ giving journals the flexibility to incorporate the recommendations and form into their policies and instructions. The ICMJE disclosure recommendations are also a floor, meaning that journals that adopt the HDF with its comprehensive disclosure requirement would still be able to capture the information suggested by the ICMJE. As emphasized in Section IV, *Adoption and Implementation of the HDF*, the HDF's success depends on the coordinated communication, shared responsibility, and wide adoption across domestic and international biomedical journals and other types of organizations. Accordingly, the HDF was carefully designed to allow stakeholders that have adopted the ICMJE's recommendations and Disclosure Form or follow other organization guidelines, to implement the HDF in entirety or specific aspects of the framework.

To help journals, professional societies, and other interested stakeholders integrate the HDF into their policies or processes, highlighted below are key areas where the HDF is consistent with the ICMJE's disclosure format and where there is divergence.

Author Disclosure and Timeframe for Disclosure

Both the HDF and the ICMJE disclosure format require authors disclose all financial interests and relationships, pertaining to the subject matter of the manuscript.

- **Harmonization Disclosure Framework** – The HDF defines this disclosure process as a “comprehensive disclosure with relevancy designations,” requesting authors designate which of those disclosed interests (e.g., financial interests or professional relationships) are relevant to the article and existed at any point within the **24 months prior** to acceptance of the submission.

¹³ International Committee of Medical Journal Editors, *ICMJE Membership*, <http://www.icmje.org/about-icmje/faqs/icmje-membership/> (last visited July 13, 2021).

¹⁴ Harmonizing Financial Disclosures in Biomedical Journals, www.aamc.org/disclosure (last visited July 13, 2021).

¹⁵ International Committee of Medical Journal Editors, *Who Should Use the Recommendations* <http://www.icmje.org/recommendations/browse/about-the-recommendations/who-should-use-the-recommendations.html> (last visited July 13, 2021).

Relevant under the HDF means directly related to the topic and subject matter of the article, including relationships with for-profit and not-for-profit entities. This information is organized within specific categories (i.e., professional services, financial stake, intellectual property, and financial support), and allows authors to provide details about each disclosure. In the interest of ensuring transparency and building public trust, authors are also asked to disclose any and all direct sources of funding support from the initial conception and planning of the research to the present, regardless of the type of funder (e.g., for-profit, not-for-profit). For additional information, see *Section I, Relevancy of Financial Interests* and *Section II., Uniform Disclosure Criteria and Process*.

- **ICMJE Disclosure Form** – Unlike the HDF, the ICMJE Disclosure Form utilizes the word “related” instead of “relevant” to describe the process by which authors designate relationships, activities, or interests that are applicable to the content of the current manuscript, defining “related” as “[...]any relation with for-profit or not-for profit third parties whose interests may be affected by the content of the manuscript.”¹⁶ Despite this difference, under both disclosure models the information requested from authors is consistent. Also consistent is the ICMJE’s request for authors to report support for their work within the confines of two disclosure periods: 1) “*since the initial planning of the work*” which includes all support for the manuscript and has no time limitation; and 2) for the “*past 36 months*.” For this time period, disclosures are organized within one of twelve categories (e.g., grants/contracts, royalties/licenses, consulting fees, payment/honoraria, payment for expert testimony, participation on a Data Safety Monitoring Board,).

The most significant difference between the HDF and ICMJE disclosure format is the HDF’s 24 month disclosure period in comparison to the ICMJE’s 36 month timeframe. The decision to use a 24 month period was done in part to alleviate the potential reporting burden on authors and journals, and broaden the potential reach of standardized disclosure requirements beyond the biomedical journal community to other stakeholders that utilize a 24 month disclosure period (e.g., CME community, society organizations). Notably, as previously discussed, the ACCME has revised its disclosure standards in ways that largely reflect the principles and recommendations of the HDF.¹⁷

While the HDF and the ICMJE’s disclosure periods differ, this should not present barriers preventing interested stakeholders from simultaneously adopting the HDF and the ICMJE Disclosure Form. As described above, both paradigms are compatible on the disclosure of all interests and relationships, across the lifespan of the work, and while the HDF utilizes a 24 month disclosure period for both comprehensive disclosure and designation of relevant financial interests and professional relationships, the journals that either require a longer period of comprehensive disclosure or ask for additional relevant (or “directly related”) interests would capture everything prescribed by either approach. Also, as previously noted, the ICMJE does not require or enforce the use of its recommendations or disclosure form, permitting journals who follow the ICMJE’s disclosure format to also adopt the HDF’s 24 month disclosure period.

It is the intention of those involved in the Harmonization Initiative to continue working towards a truly harmonized and consistent approach to disclosure across all stakeholders.

¹⁶ ICMJE Disclosure Form, *See Note 2*.

¹⁷ Changes to the Standards for Integrity and Independence in Continuing Medical Education, *See Note 9*.

Additional Similarities and Distinctions Between the HDF and ICMJE Disclosure Format

There are a few other similarities and distinctions between the HDF and ICMJE's disclosure format that are worth highlighting.

- **Disclosure Categories**– The HDF and the ICMJE disclosure form use comparable categories for disclosure, those that were developed by a MedBiquitous working group and are listed in the Appendix. This alignment of financial interest and professional relationship types greatly increases opportunities for streamlining and collecting disclosures for different types of organizations in a single electronic platform.
- **Updating Disclosures after Manuscript Acceptance but Before Publication** – A foundational component of the HDF is the “comprehensive disclosure” of all financial interests and professional relationships (with a relevancy designation) to ensure the complete and accurate reporting of this information. To help capture *additional relevant* interests during this timeframe, authors should be provided with an opportunity to clarify or correct disclosure errors or omissions *after acceptance of the manuscript but before publication* (See Section II, *Uniform Disclosure Criteria and Process*). While the ICMJE does not provide specific recommendations on whether authors should update their disclosures *before* publication of a manuscript, the ICMJE and other organizations such as COPE, have clear standards regarding corrections and retractions *after* publication. The HDF supports the publication of a corrective notice with the author's explanation of expression or regret, and in Section III, *Principles of Accountability*, recommends that stakeholders reference the standards and procedures set forth by key organizations (e.g., ICMJE) regarding corrections, errata, statements of concern, and formal apologies for failure to disclose.

Financial Interests and Professional Relationships of Immediate Family Members

- Both the ICMJE disclosure form and the HDF allow for disclosure of certain financial interests and professional relationships of an author's immediate family (i.e., spouse and dependent children) but the HDF is more prescriptive on *when* and *where* this information should be disclosed. In the HDF rubric, such interests should be disclosed when relevant to the topic and subject matter of the article and captured in the *Other Financial Interests and Professional Relationships* question. The HDF clarifies that these disclosures should not be included in the author's comprehensive disclosure out of concern for the accurate reporting of relationships, potential for public misinterpretation, and inappropriate sharing of private information.
- **Institutional Interests**
Both the HDF and the ICMJE Disclosure Form are capable of capturing authors' institutional interests and neither require that authors routinely report this information to biomedical journals. The HDF is prescriptive that institutional interests should be disclosed only if the author has “specific knowledge” of the financial interests and professional relationships directly related to the specific work, *and* the author *wishes* to disclose that interest. Thus, the disclosure of institutional interests is optional and discretionary given the impracticality and infeasibility related to the disclosure of this type of information.

The ICMJE's updated Disclosure Form does not explicitly request that authors provide information about institutional interests, a clear departure from the previous disclosure form (i.e., *ICMJE Form for Disclosure of Potential Conflicts of Interest*) which requested disclosure of “[...] all sources of revenue paid (or promised to be paid) directly [to the author] or [their] institution [...]” Without explicitly requesting that authors provide information about institutional interests, the updated ICMJE Disclosure Form provides an opportunity for authors to report those interests when reporting information about disclosures from the past 36 months in the “Other financial or non-financial interests” category.

Appendix

Uniform Disclosure Criteria and Related Information

PROFESSIONAL SERVICES	
Relationship Type Categorization	Information Required
Employment (secondary or ancillary employment outside of one's primary affiliation)	- Entity Name - Title
Fiduciary Role	- Entity Name - Title/Role
Independent Contractor	- Entity Name - Category of Service Provided <ul style="list-style-type: none"> o Consultant/Speaker o Data and Safety Monitoring o End Point Review Committee o Expert Witness o Other
FINANCIAL STAKE	
Relationship Type Categorization	Information Required
Stock	- Entity
Stock Option	- Entity
Other Securities	- Entity
Other Business Ownership	- Entity - Description
INTELLECTUAL PROPERTY	
Relationship Type Categorization	Information Required
Patent or Published Patent Application	- Description - Patent Status - Patent Holder/Owner - Licensee, if applicable
Copyright, Royalties, Other Licensed Intellectual Property	- Description - IP Holder/Owner - Licensee (if applicable)
FINANCIAL SUPPORT	
Relationship Type Categorization	Information Required
Gift	- Entity Name
Grant/Contract	- Entity Name - Purpose/Type of Support