CRA Policy on Potential Conflicts of Interest in the Guideline Development Process

1. Policy Objective

1.1. This document is a guide to help self-identify and disclose potential conflicts of interest (COIs) for all stakeholders involved in the development of guidelines and policy statements endorsed by the CRA.

1.2. The goal of this process is to facilitate trust and transparency between the CRA, patients, physicians, payers, policy makers, the public, and all other involved parties.

1.3. The CRA recognizes that most experts in their field will have potential COIs to disclose and that many of these potential COIs can be appropriately managed without limiting participation.

2. Disclosure Requirements

2.1. Guideline panel members (defined as those directly involved in developing guidelines under the direction of a Guideline Lead) should disclose any potential COIs three years retrospectively from the start and throughout the development process (should their COI declaration change). CRA staff will remind guideline panel members of this responsibility on a yearly basis. It is inherently difficult to define and assess impacts of potential COIs; thus, the CRA recommends being overly inclusive.

2.2. Potential COIs that we recommend disclosing include, but are not limited to:

- Sources of income or reimbursement by means of honoraria, royalties, speaking fees, ad boards, witnesses, intellectual properties, patents, investments, advocacy, consulting and/or serving on a board of directors.
- A direct financial relationship with an organization that has an interest in the contents of the guideline including those with competing intellectual properties.
- Involvement in relevant clinical trials and industry supported research.
- Participation in relevant government policy, patient advocacy, investigator driven research and other roles outside of industry that may not be traditionally thought of when considering ones potential COIs.

2.3. Guideline panel members should also disclose the following potential COIs even if they occurred outside of three years:

- If they were the principal investigator of a study that evaluated a treatment, intervention, assessment tool, or other intellectual property mentioned in the contents of the guideline or policy.

3. Disclosure Tool

3.1 At the start of their involvement, guideline panel members should submit a Conflict of Interest form from the International Committee of Medical Journal Editors (ICJME) to their Guideline Lead, to be reviewed and then forwarded to the Guidelines Committee Chair and CRA Committee Coordinator. (A list of guideline panel members must be provided to the CRA Committee Coordinator to ensure all forms are received.) The form is available at http://www.icmje.org/conflicts-of-interest/.

3.2. Potential COIs that arise during development process should also be reported by submitting an updated form.

3.3. All Guideline Committee members (regardless of participation on a guideline panel) should submit a CRA Code of Ethics and Disclosure form annually: https://ca.surveygizmo.com/s3/50044375/2019-Code-of-Ethics-Disclosure. The CRA Committee Coordinator will ensure the collection of these forms annually.

4. Ensuring Transparency of Reported Potential COIs

4.1. At a minimum, the reported potential COIs of individual guideline panel members should be reviewed on a case by case basis by the Guideline Lead, disclosed within the working group to facilitate discussion, and be presented to the broader Guidelines Committee and Guidelines Committee Chair for review prior to submission for publication or formal endorsement of a guideline by the CRA.

4.2. We recommend going beyond this by maintaining an open dialog between stakeholders, committees, the working group, and CRA member base throughout the process to promote transparency.

4.3. Publications and statements endorsed by the CRA should have recognized potential COIs listed.

4.4. The potential COIs disclosed by members of the Guidelines Committee on an annual basis should be summarized by the CRA Committee Coordinator and be accessible to CRA leadership on request.

5. Management of COIs

5.1. The presence of a potential COI should not automatically disqualify a guideline panel member or committee member; rather, it should serve to foster self-disclosure, peer review, and self-awareness of potential biases regarding the individual components and recommendations that comprise guidelines and policy statements.

5.2. Guideline Committee members should self-recuse and abstain from voting if they feel conflicted when approving each individual component or statement. Guideline Leads and the Guideline Committee Chair(s) should also review disclosures to identify potential conflicts and discuss with individual(s) ahead of time regarding participation/voting for individual recommendations.

6. References

6.1. Guidelines from the ACR, BSR, EULAR, and WHO regarding COIs were consulted and contributed to the development of this policy.

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