

## Appendix A

### Chart: ASNC Risk Assessment & Automatic COI Resolutions

Reported COI Risk Level	Action for COI Resolution for Writing Committee Members & REVIEWERS*
<p>Level 1 (No or Low Risk):</p> <ul style="list-style-type: none"> <li>• No Financial Relationships; or</li> <li>• Relationships are NOT relevant to clinical document; or</li> <li>• Contributor has already eliminated relationship within past 12 months.</li> <li>• Research Grant or Research Contractor (with funds provided to the researcher's institution)</li> </ul>	<ul style="list-style-type: none"> <li>• Signed Recusal and Attestation</li> <li>• Disclosure to audience.</li> </ul>
<p>Level 2 (Moderate Risk):</p> <p>Individual has relevant financial relationships with one or more commercial interests, including:</p> <ul style="list-style-type: none"> <li>• Relationships with commercial supporter(s) of the clinical document topic; and/or</li> <li>• Intellectual property rights, Consulting Fees, Honoraria, Research Grant or Research Contractor (with funds provided directly to the researcher), Advisory Board</li> </ul>	<ul style="list-style-type: none"> <li>• Signed attestation to non-biased, evidence based recommendations.</li> <li>• A chair with no more than a moderate risk relevant COI must be paired with a co-chair with no relevant COI.</li> <li>• Quality Committee will approve final writing group composition.</li> <li>• The member is permitted to participate in the discussions and to draft or vote on a recommendation or corresponding text however, these sections must be reviewed by the chairperson or co-chair with no relevant COI to eliminate bias and ensure balanced content.</li> <li>• The Quality Committee chair and the Writing Committee chair or co-chair with no relevant COI will determine if further action is needed.</li> </ul>
<p>Level 3 (High Risk):</p> <p>Fees received from commercial interest for <u>promotional</u> services, (e.g. Speakers Bureau).</p>	<ul style="list-style-type: none"> <li>• Standard resolutions above will be in effect.</li> <li>• Whenever possible, assign the conflicted member of the writing committee with an assignment that does not represent content relevant that may note a conflict. If a relevant conflict does exist, and it is determined the member should contribute, then the member must be paired with a member with NO relevant conflicts. Writing Committee chair or co-chair with no relevant COI will determine if additional review or action is needed.</li> </ul>
<p>Level 4 (Very High Risk):**</p> <ul style="list-style-type: none"> <li>• Royalty;</li> <li>• Stock Interest (e.g.: stocks, stock options or other ownership interest, excluding diversified mutual funds)</li> </ul>	<ul style="list-style-type: none"> <li>• Restrictions Required. If a conflict is disclosed that is identified as royalty or stock interest, the chair or co-chair with no relevant COI must limit the role of the member to writing sections not directly related to the royalty or stock interests.</li> <li>• If the expertise of the conflicted member cannot be replicated by an alternate writing committee member, then the conflicted member may be allowed to contribute to writing of the specific area of conflict, however, the member must be paired with a member of the writing committee that has no relevant conflicts. In addition, the section must be reviewed by non-conflicted members of the writing committee, the Education Committee and the Board of Directors to insure standard resolutions for "Moderate" and "High risk" will be in effect.</li> </ul>

<p>Level 5 (Highest risk)** Industry Employee or Owner</p>	<ul style="list-style-type: none"> <li>• In general, members of industry, employees or owners are not permitted to contribute content to clinical documents.</li> <li>• If the expertise of the conflicted member cannot be replicated by an alternate writing committee member, then the conflicted member may be allowed to contribute to writing of the specific area of conflict, however, the member must be paired with a member of the writing committee that has no relevant conflicts. In addition, the section must be reviewed by non-conflicted members of the writing committee, the Education Committee and the Board of Directors to insure standard resolutions for “Moderate” and “High risk” will be in effect.</li> </ul>
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\* Staff will always ask COI reviewer if additional resolutions are needed (e.g. limit involvement to aspects not related to reported conflict); and DOCUMENT the reviewer’s reply.

\*\* ASNC policy: Employees or owners of commercial interests may only serve as writing committee members if the committee is comprised of more than 50% of its members with no relevant conflicts and the content of the member with relevant conflicts is specifically reviewed by a writing committee with no relevant conflicts. Other very high risk relationships, such as stock interest, may participate without additional review only if the content does NOT relate to the business lines, products, or services of the commercial interest. If the content of the clinical document that the stock holder of the commercial interest controls relates to the business lines and products of its employer, additional review will be required by a member of the writing committee that has no relevant conflicts.

Approved by the Board of Directors, February 2, 2017