



Conflict of Interest Management Guidelines November 2012

The Association places volunteers and staff in key roles because of the expertise they bring to that role. In developing and maintaining that expertise, individuals may be involved in outside transactions or business relationships that overlap with the work of the Association. These relationships contribute to the strength and knowledge of the Association, but must be disclosed and assessed against pending decisions and actions for potential conflicts.

Implementation guidance is provided in this document to manage potential conflicts of interest for Individuals serving in the following key ADA roles:

- Executive Committee
- Board of Directors
- Board Committees
- *Ad hoc* Guideline Writing Groups
- Journal Editors
- Community Leadership Board Members
- Senior Staff

Policies and procedures to manage potential conflicts of interest related to ADA research grant awards are included in the documents "Research Grant Process Conflict of Interest Safeguards" and "Conflict of Interest, Confidentiality, and Non-Disclosure Policy for Grant Application Reviewers."

To develop COI implementation guidance, the typical responsibilities of each role were compared against likely outside transactions and business relationships that may overlap with the work of the Association. These transactions and business relationships are grouped into three categories:

- I. Transactions with the American Diabetes Association
- II. Transactions and relationships with Industry
- III. Transactions and relationships with Other Companies/Organizations

Disclosure, Recusal and Restriction Guidance

For each category of transactions and business relationships, the following pages provide guidance to manage the potential conflicts of interest for individuals serving in key ADA roles. The guidance includes which transactions/relationships should be disclosed as a potential conflict of interest. The annual conflict of interest disclosure process is managed by the Association's Legal Affairs Division under the review of the Conflict of Interest SubCommittee.

The guidance also provides additional information to implement disclosure and recusal guidance. Chairpersons and senior staff of the respective Committee/Group will determine whether a potential conflict of interest requires recusal from vote and/or discussion in compliance with these guidelines. Members of the Audit Committee, the COI SubCommittee and the Vice President of Legal Affairs can assist when the appropriate steps to manage the potential conflict are not readily determined.

The Audit Committee has the Board designated responsibility to ensure appropriate conflict of interest policies/procedures are developed and implemented. With regard to conflicts on an issue specific to the Board of Directors, the Chair of the COI SubCommittee and Vice President of Legal Affairs will determine the appropriate action to manage the conflict in consultation, as appropriate, with the Chief Executive Officer and Principal Officers. If the COI SubCommittee Chair is not present at a Board meeting when a COI issue arises that requires an immediate determination, another current member of the COI SubCommittee or Audit Committee will act in the Chair's place. If the VP of Legal Affairs is not present at a meeting when a COI issue arises that requires an immediate determination, the Chief Financial Officer will act in the Vice President's place.

Restricted transactions/relationships are those which should not take place while the individual is serving in the key ADA role. Rare and extenuating circumstances may exist that make it reasonable to waive the restriction requirement for a specific individual. In such cases, information may be submitted to the COI SubCommittee requesting a waiver. The SubCommittee will provide a recommendation to the Executive Committee for final determination.

Additionally, the disclosure, restriction and recusal guidance also applies when an **immediate family member** of an individual serving in a key ADA role is involved in one of the listed transactions/relationships. The Code of Virginia defines *immediate family members* related to conflicts of interest in procurement as spouse/domestic partner, sons, daughters, parents, brothers, sisters, and any person living in the same household as the individual.

I - TRANSACTIONS WITH THE AMERICAN DIABETES ASSOCIATION

For individuals serving in a key ADA role, as listed on Page 1, the following disclosure and recusal guidance is provided for transactions involving the Association:

Disclose transactions with ADA. Recuse based on specific issues under consideration.

Individuals serving in any key ADA role should disclose all transactions with the American Diabetes Association and the related dollar amount, including the following. Individuals should recuse themselves as appropriate based on a specific issue under consideration. Additional guidance on disclosure/recusal is provided.

1. Individual's employer receives an ADA research grant in which the individual is named as a principal investigator, sub-investigator or other major professional role. Specifically note the individual's role on the grant.
2. Individual's employer receives an ADA grant other than research (e.g., community outreach grant) in which the individual is named for a role in the funded program. Specifically note the individual's role on the grant.
3. Individual is a direct recipient of a grant or honoraria from ADA (e.g., campership)
4. Individual is an employee/ partner/ owner of a company providing goods or services to ADA. Specifically note if individual is directly involved.

RESTRICTIONS

Certain transactions are likely to create a perceived conflict of interest to an extent that would jeopardize the credibility of a particular ADA role. As a result, individuals should not engage in the following transactions/relationships while serving in the key ADA role indicated:

<u>ADA Roles</u>	<u>Restricted Transaction/Relationship</u>
Senior staff	1. Employee/partner/owner of a company providing goods or services to ADA
Voting Board member	1. Compensation for any service provided to ADA

Additional Disclosure/Recusal Guidance – Transactions with ADA

- A standing grant disclosure will be prepared by ADA for each Executive Committee, Board of Directors, Research Policy Committee, Finance Committee and Research Grant Review Committee meeting. The disclosure will indicate the amount of ADA grants awarded to an employer of an individual participating in the meeting and whether that individual is named as a principal investigator or other role on the grant.
- Any business transaction between ADA and an individual serving in a key ADA role must be conducted as an arms-length transaction (i.e., conducted as if the individual were not serving in an ADA role). The priority is to ensure the individual, or his/her organization, does not inappropriately benefit from the transaction. The individual serving in the key ADA role must be recused from voting on the transaction or any action that would affect the terms of the transaction. Due diligence should be conducted by individuals without related conflicts to determine whether the Association could obtain a more advantageous transaction/ arrangement from an unconflicted person or entity.

Typically, the individual involved can provide valuable information to the decision-making group regarding the substance of the proposed transaction. After such discussion, the individual must then leave the room and allow discussion to continue in the individual's absence. The vote will also take place with the individual absent from the room. Those who remain in the room should not disclose the way in which individual members voted. These additional steps will further ensure that decisions are made without the influence of a conflict of interest. The meeting minutes must document the disclosure, recusal, and absence from the room.

- A member of the Board of Directors may choose to accept a traditionally compensated position, such as a journal editor-in-chief. In lieu of the traditional compensation, the forfeited amount will be credited toward the Board member's give/get fundraising requirement and acknowledged as a contribution to the Board member's program of choice. Board members will be reimbursed for expenses under the same guidelines as other individuals serving in comparable positions.

II – TRANSACTIONS AND RELATIONSHIPS WITH INDUSTRY

For individuals serving in a key ADA role, as listed on Page 1, the following disclosure and recusal guidance is provided for transactions involving Industry. *Definition of Industry:* Any corporation, partnership, sole proprietorship, or other legal entity, both for profit and not-for-profit, engaged in the manufacture, distribution, sale, or reimbursement of diagnostic or therapeutic drugs, devices, supplies, or service for clinical care, research, or education. This definition does not include a physician or other clinician’s practice plan, or reimbursement for clinical services provided to a clinician’s patients. It does not include professional associations, not-for-profit volunteer health organizations, academic institutions or hospitals that provide products or services related to medical care, medical research; or accredited medical education. Examples include pharmaceutical companies and medical device companies.

Disclose transactions/relationships with Industry. Recuse based on specific issues under consideration.

Individuals serving in any key ADA role should disclose all transactions with Industry and indicate whether the related amount exceeds \$10,000, including the following. Individuals should recuse themselves as appropriate based on a specific issue under consideration. Additional guidance on disclosure/recusal is provided.

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| <ol style="list-style-type: none"> 1. Individual’s employer receives Industry research funding and the individual is directly involved. 2. Individual is a direct employee or paid consultant to Industry. 3. Individual is a recipient of other Industry benefits, such as travel. 4. Individual is a participant in a speaker’s bureau sponsored by Industry. | <ol style="list-style-type: none"> 5. Individual is a member of an Industry advisory board or an instructor/speaker at a CME sponsored by Industry. 6. Individual is a stockholder/investor of an Industry company or inventor of a diabetes-related product. 7. Individual is an employee/ partner/ owner of a company providing goods or services to Industry, and the individual is directly involved. |
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RESTRICTIONS

Certain transactions with Industry are likely to create a perceived conflict of interest to an extent that would jeopardize the credibility of a particular ADA role. As a result, individuals should not engage in the following transactions/ relationships while serving in the key ADA roles indicated:

ADA Roles	Restricted Transaction/Relationship
Professional Practice Committee Chair	<ol style="list-style-type: none"> 1. Direct employee of Industry 2. Paid consultant of Industry 3. Participant in speaker’s bureau sponsored by Industry
Advocacy Committee Chair, Legislative SubCommittee Chair, Finance Committee Chair, Journal Editors-in-Chief	<ol style="list-style-type: none"> 1. Direct employee of Industry 2. Paid consultant of more than \$10,000/year to a single Industry company 3. Participant in speaker’s bureau sponsored by Industry
Executive Committee	<ol style="list-style-type: none"> 1. Direct employee of Industry 2. Participant in speaker’s bureau sponsored by Industry
Immediate Past Officers, Other Board Committee Chairs	<ol style="list-style-type: none"> 1. Direct employee of industry
Senior staff	<ol style="list-style-type: none"> 1. Direct employee of Industry 2. Paid consultant to Industry 3. Participant in speaker’s bureau sponsored by Industry 4. Direct recipient of other Industry benefits, such as travel 5. Member of an Industry advisory board or an instructor/speaker at a CME sponsored by Industry.

Additional Disclosure/Recusal Guidance – Transactions and Relationships with Industry

- If an individual receives Industry funding as a principal investigator, employee or consultant, that individual should be recused from voting on any ADA transaction or policy decision that is directly and specifically related to the Industry company providing the funding.

The individual involved may be able to provide valuable information to the decision-making group regarding the substance of the proposed transaction or policy. After such discussion, the individual must then leave the room and allow discussion to continue in the individual's absence. The vote will also take place with the individual absent from the room. Those who remain in the room should not disclose the way in which individual members voted. These additional steps will further ensure that decisions are made without the influence of a conflict of interest. The meeting minutes must document the disclosure, recusal, and absence from the room.

- The memberships of the Professional Practice Committee and *ad hoc* guideline writing groups should include the Chair and a majority in each Committee/Group who do not receive any Industry funding as an employee, consultant, or principal investigator specific to the activities of the Committee/Groups. Other members of the Committee/Groups should disclose Industry relationships/ transactions and recuse themselves from voting on any ADA transaction, policy decision or position that is directly and specifically related to the Industry funding.
- The membership of the Finance Committee, the Advocacy Committee and the Legislative Subcommittee should include a majority in each Committee who do not receive Industry funding as an employee, consultant, or principal investigator. Other members of the Committee should disclose Industry relationships/ transactions and recuse themselves from voting on any ADA transaction, policy decision or position that is directly and specifically related to the Industry funding.
- Participating as a speaker at a CME sponsored by Industry is considered a potential COI sufficiently managed by disclosure if the CME is appropriately accredited and designed to be independent, free of commercial bias, and based on valid content.
- Disclosure and recusal guidance apply irrespective of whether an individual's transaction with Industry relates to diabetes or another operational area of the Industry company.
- Consideration should be given to recuse an individual from representing ADA as a media spokesperson based on the level of involvement with Industry.

III – TRANSACTIONS AND RELATIONSHIPS WITH OTHER COMPANIES/ORGANIZATIONS

For individuals serving in a key ADA role, as listed on Page 1, the following disclosure and recusal guidance is provided for transactions and relationships involving other companies/organizations.

Disclose transactions/relationships with other organizations. Recuse based on specific issues under consideration.

Individuals serving in any key ADA role should disclose the following transactions and relationships with other companies/organizations and indicate whether a financial benefit exists in excess of \$10,000. Individuals should recuse themselves as appropriate based on a specific issue under consideration. Additional guidance on disclosure/recusal is provided.

1. Individual serving as a senior volunteer to another nonprofit or charity
2. Individual employed as senior staff of another nonprofit or charity that is not diabetes-related
3. Individual benefits financially from a 3rd party because of a decision/action by ADA

RESTRICTIONS

Certain transactions with other organizations are likely to create a perceived conflict of interest to an extent that would jeopardize the credibility of a particular ADA role. As a result, individuals should not engage in the following transactions/ relationships while serving in the key ADA roles indicated:

<u>ADA Roles</u>	<u>Restricted Transaction/Relationship</u>
All	1. Senior staff of another diabetes-related nonprofit/charity
Executive Committee, Board of Directors, Board Committee Chairs	1. Senior volunteer of another charity whose mission/strategy would make it inappropriate to share proprietary fundraising or other operational information.
Senior staff	1. Senior volunteer of another charity whose mission/strategy would make it inappropriate to share proprietary fundraising or other operational information 2. Financial beneficiary from a 3 rd party because of a decision/action by ADA.

Additional Disclosure/Recusal Guidance – Transactions and relationships with other organizations

- An individual serving as a senior volunteer or staff to another nonprofit/charity should be recused from voting on any ADA transaction or policy decision that is directly and specifically related to the other nonprofit or charity. The individual involved may be able to provide valuable information to the decision-making group regarding the substance of the proposed transaction or policy. After such discussion, the individual must then leave the room and allow discussion to continue in the individual's absence. The vote will also take place with the individual absent from the room. Those who remain in the room should not disclose the way in which individual members voted. These additional steps will further ensure that decisions are made without the influence of a conflict of interest. The meeting minutes must document the disclosure, recusal, and absence from the room.
- An ADA decision or action could result in financial benefit from a 3rd party to an individual in a key ADA role. Examples: ADA support of provider reimbursement to a specific healthcare professional could lead to a financial benefit from insurance companies. ADA support of a legal advocacy initiative could lead an attorney or expert witness to be engaged by plaintiffs. Individuals should disclose a potential financial benefit and should be recused from a vote that would directly and specifically benefit the individual.