

NATIONAL INSTITUTES OF HEALTH COMMITTEE MANAGEMENT HANDBOOK

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CONFLICT OF INTEREST CERTIFICATION FOR NON-MEMBER ATTENDANCE AT CLOSED SESSION MEETINGS OF NATIONAL ADVISORY COUNCILS

A conflict of interest exists when a non-member attendee serving as a reviewer, discussant or presenter has an interest in a grant application/contract proposal or discussion that is likely to bias the review or outcome of the discussion. A reviewer who has a real conflict of interest with an application/proposal or discussion being held at the closed session of the meeting may not participate in the closed session of the meeting. Appearance of a conflict of interest should be avoided when possible but, if the Executive Secretary managing the committee determines that the integrity of the process would not be impaired and no other practical means exist for securing the necessary expertise, the individual may participate in the segment of the meeting they were invited as presenter, discussant, or reviewer.

Non-member attendees are most familiar with their own situation, and it is their personal responsibility to bring to the attention of the Executive Secretary any conflict of interest situations that may be relevant. A non-member attendee must certify that they will not be and have not been involved in the review of any application/proposal or discussion being held at the closed session of the meeting. The following guidance will assist in determining whether a real or apparent conflict of interest exists. The guidance is not all-inclusive, due to the nature of the conflict of interest subject matter. Therefore, the Executive Secretary should be consulted when there is any question about participation in the particular segment of the closed session of the meeting the non-member is invited to attend.

Bases for Conflicts of Interest

Real Conflict of Interest: There are several bases for a real conflict of interest: employment, financial benefit, personal, or professional. Any one may serve to disqualify a non-member from participating in a review or discussion being held at the closed session of the meeting.

Employment: A non-member attendee who is a salaried employee, whether full- or part-time, of the applicant institution or who is negotiating with the organization for employment shall generally be considered to have a conflict of interest with regard to applications/ proposals from or discussion concerning that organization. However, in large organizations or multi-component organizations there may be circumstances where the components are sufficiently independent that an employee of one component can review or discuss an application/ proposal from another component without a real conflict of interest. Participating in a council meeting discussion or review of an application/proposal does not make an individual an employee or officer of the Federal Government.

Financial Benefit: Where a non-member attendee has received or could receive direct financial benefit of any amount, other than from employment, from an applicant institution or principal investigator related to the application under review. Regardless of the level of financial

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involvement, if the individual feels unable to provide objective advice, they must recuse themselves from the review of the application/proposal at issue or discussion being held at the closed session of the meeting.

Relatives or Associates: A conflict of interest exists if a close relative or professional associate of a non-member attendee submits an application/proposal, or receives or could receive financial benefits from or provides financial benefits to an applicant. In such case, it will be treated as the non-member attendee's financial benefit.

Appearance of Conflict of Interest: Where there is an appearance of conflict of interest, but not sufficient grounds for disqualifying the non-member attendee, the Executive Secretary will document: (1) that there is no real conflict of interest; and (2) that, at the time of the review or discussion being held at the closed session of the meeting, no practical alternative exists for obtaining the necessary scientific advice from the non-member attendee with the apparent conflict. Four specific examples of potential concern include:

- 1.) When a non-member participant or immediate family member holds financial, equity, or patent interest in an organization whose product or product concept is involved in the deliberations;
- 2.) When a non-member participant or immediate family member holds financial, equity, or patent interest in an organization whose product or product concept competes with a product or product concept being discussed;
- 3.) When a non-member participant or immediate family member is seeking employment in an organization or serves as an officer, director, trustee, general partner, or employee of an organization whose product or product concept competes with, is involved in the deliberations, or would benefit from research in a defined area; and
- 4.) When a non-member participant or immediate family member holds financial, equity, or patent interest in an organization whose product or product concept would uniquely benefit from research emphasis in a defined area.

Confidentiality and Non-Disclosure of Materials and Proceedings

The applications/proposals and associated materials made available to a non-member attendee, as well as the discussion that takes place during the closed sessions of the meeting, are strictly confidential and must not be disclosed to or discussed with anyone who has not been officially designated to participate in the meeting. A non-member attendee must certify on the Conflict of Interest Certification associated with this information sheet that they will maintain the confidentiality of the review and not disclose this information to any other individual except as authorized by the NIH official in charge of the meeting.

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AT CLOSED SESSION MEETINGS OF NATIONAL ADVISORY COUNCILS**

Committee Name: _____ Date of Meeting: _____

Name of Non-Member Attendee: _____

Primary Employer: _____

Address: _____

Other Employers (if applicable):

Reason for Attending:

- Reviewer
- Presenter
- Discussant
- Training/Orientation

I have read the attached "NIH Conflict of Interest, Confidentiality, and Non-Disclosure Rules and Information for Non-Member Attendees..." and have examined the list of grant applications/contract proposals to be reviewed or the meeting's agenda, and hereby certify that, based on the information provided to me, **I do not have a conflict of interest in any of them.**

I have read the attached "NIH Conflict of Interest, Confidentiality, and Non-Disclosure Rules and Information for Non-Member Attendees..." and have examined the list of grant applications/contract proposals to be reviewed or the meeting's agenda, and hereby certify that, based on the information provided, I have a conflict of interest and hereby recuse myself from their review or discussion.

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I fully understand the confidential nature of the discussion held during the closed session of the NIH advisory committee meeting and agree: (1) to destroy or return all materials related to it; (2) not to disclose or discuss the materials associated with the meeting or my evaluation with any other individual except as authorized by the designated Federal official; and (3) to refer all inquiries concerning the review to the Government official managing the committee.

Signature: _____

Date: _____