

**ADA CERP
STANDARD V. COMMERCIAL OR PROMOTIONAL
CONFLICT OF INTEREST**

SAMPLE POLICES AND FORMS

This document includes samples of policies, guidelines and forms related to ADA CERP Recognition Standard V. The ADA CERP offers these examples as resources for providers of continuing dental education. Included are:

- Sample policies for commercial support and conflict of interest
- Sample letters of agreement for commercial support
- Sample conflict of interest declaration forms for instructors

Because organizational structure and commercial relationships of CE providers vary greatly, several examples of each document are provided. These examples are offered for use as models. Providers may tailor the documents to the specific characteristics of their individual programs. Providers are not required to use these exact documents. Use of these documents will not guarantee that a program will be found in compliance with Standard V.

NATIONAL DENTAL ORGANIZATION SAMPLE POLICY

XXXXXXXX [Name of CE Provider] Guidelines Regarding Commercial Support and Conflict of Interest

The XXXXXXXX, in planning continuing education programming for the XXXXXXXX Meeting, will adhere to the following policies:

1. Program topic selection will be based on perceived needs for professional information and not for the purpose of endorsing specific commercial drugs, materials, products, treatments, or services.
2. Funds received from commercial sources in support of any educational programs shall be unrestricted and the XXXXXXXX Committee shall retain exclusive rights regarding the selection of presenters, instructional materials, program content and format, etc.
3. Any and all commercial support received shall be acknowledged in program announcements, brochures, and the on-site program book.
4. Commercial support shall be limited to:
 - a. the payment of reasonable honoraria;
 - b. reimbursement of presenters' out of pocket expenses; and
 - c. the payment of the cost of modest meals or social events held as part of an educational activity.
5. Presenters shall be instructed to avoid recommending or mentioning any specific product by its trade name, using generic terms whenever possible. When reference is made to a specific product by its trade name, reference shall also be made to competitive products.
6. Speakers will be required to disclose any potential bias to commercial supporters of any activity related to the XXXXXXXX Meeting.

The XXXXXXXX shall:

1. Be responsible for the content, quality, and scientific integrity of all CDE activities.
2. Assure that presentations give a balanced view of all therapeutic options.
3. Assure that commercial exhibits do not influence planning nor interfere with the presentation of CDE activities.
4. Be responsible for making ultimate decisions regarding funding arrangements for CDE activities.
5. Assure that commercially supported social events at CDE activities do not compete with, nor take precedence over, the educational events.
6. Have a policy on conflict of interest and assure that all CDE activities conform to this policy.

DENTAL SCHOOL SAMPLE POLICY

XXXXX [Name of CE Provider] Standards for Commercial Support of Continuing Education Courses

Commercial fiscal support can contribute significantly to the quality of certain continuing education activities. However, the utilization of commercial support must be appropriately handled in order to safeguard any potential conflict of interest problems. The following standards have been developed to provide guidelines for use during the planning, designing, implementation and evaluation stages of continuing education course development.

All continuing education activities offered by the XXXXX of Dentistry must adhere to the following standards:

1. Each course must offer a balanced view of all diagnostic and therapeutic options regardless of the amount of fiscal support.
2. The ultimate decision regarding funding arrangements for the planned course will be the responsibility of the Chairperson of the Department through which the course is planned.
3. Funds from a commercial source must be in the form of an educational grant made payable to the XXXXX of Dentistry Continuing Education Department. Payment for expenses incurred for the course will be made through the CE Department account.
4. Commercial support must be acknowledged in the printed announcements and brochures and references cannot be made to specific products or services.
5. Commercial exhibits should not in any way affect the educational content or integrity of the course activities.
6. Commercially supported social events or meals held in conjunction with educational courses must in no way take precedence over the educational events.
7. All attendees at continuing education courses with commercial support must pay a reasonable registration fee, although subsidies may reduce the required registration fee.
8. Full disclosure of any potential conflict of interest is required. Potential conflicts of interest include, but are not limited to, the following: research funds, holding stock in the company lending fiscal support, receiving fees and etc.

COMMERCIAL ORGANIZATION SAMPLE POLICY

XXXXXXXX [Name of CE Provider] Guidelines for Conflict of Interest or Full Disclosure

XXXXXXXX provides a range of educational activities for the dental profession. When Continuing Education Credits are offered, the program is to be strictly educational and by definition, non-promotional. When the activity does not offer continuing education credits, it is promotional, shall be clearly identified as such, and is subject to regulation under the labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act. The following guideline contains the procedures under which XXXXXXXX will engage in educational activities.

Promotional Seminars and Activities:

1. Promotional Seminars are designed to provide the dental profession with the knowledge and skills necessary to effectively use XXXXXXXX products in their practice, prescribe XXXXXXXX products, or recommend XXXXXXXX products to their patients.
2. These seminars or other similar activities are clearly promotional in nature and are *fully disclosed* as promotional, both when scheduling a seminar and during its presentation.
3. No unapproved uses are discussed.
4. While every effort is made to provide the dental profession with scientific data regarding these products, *no continuing education credit or certificate is awarded for participation in such a seminar.*
5. These activities are subject to regulation under the labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act.

Continuing Education Activities:

1. Continuing education activities are to be educational and non-promotional.
2. Activities are to be independent from the promotional influences of the marketing department.
3. To ensure that these activities are educational and non-promotional, XXXXXXXX follows the guidelines of professional organization(s) and also has a Continuing Education Advisory Committee.
4. The Advisory Committee is fully responsible for ensuring that activities are educational and scientific, and free of promotional influences.
5. Generic names will be used for any discussion of a product and there will be a balanced presentation of competing therapies and any limitations of the data.
6. The Advisory Committee members are not financially compensated (beyond travel expenses for meetings).
7. XXXXXXXX will not have any promotional activities in the same room or in an oblique path to the educational activity, unless there is a designated area for general exhibits including exhibits from competing companies.
8. Sponsorship by XXXXXXXX is *fully disclosed*.
9. The relationship between any instructor and XXXXXXXX is *fully disclosed*.
10. The relationship between any instructor and any competing company that may represent a conflict of interest for the instructor is also *fully disclosed*.
11. A *conflict of interest* for an instructor would include, but it is not limited to, any personal or immediate family financial interest (i.e. consulting fees, company employee, or corporate stock) in XXXXXXXX or any competing company, or the awarding of or competing for any XXXXXXXX or competing company research grant.
12. There will be opportunity for debate in panel discussions and small group discussions.

PRIVATE ORGANIZATION SAMPLE POLICY

**XXXXXXXX [Name of CE Provider]
POLICY REGARDING COMMERCIAL SUPPORT/CONFLICT OF INTEREST**

It shall be the policy of XXXXXXXX to:

1. Avoid recommending or mentioning any specific product by its trade name. When reference is made to a specific product by its trade name, reference shall also be made to competitive products as well.
2. Program topic selection shall be based upon a perceived need for professional education and not for the purpose of endorsing specific commercial drugs, products, treatments or services.
3. Funds received from commercial sources in support of any of XXXXXXXX educational programs shall be unrestricted in that XXXXXXXX shall retain exclusive rights regarding the selection of lecturer/author, instructional materials, program content, etc.
4. Any or all commercial support received shall be acknowledged in writing in program announcements, brochures, etc.
5. Commercial support shall be limited to:
 - a. the payment of reasonable honoraria; reimbursement of out-of-pocket expenses for lecturer/author;
 - b. the payment of the cost of modest meals or social events held as part of an educational activity and;
 - c. documentation of fund expenditures for specific programs shall be maintained both by XXXXXXXX and any commercial sources of said funds; each shall render a report to the other regarding such expenditures.

NATIONAL DENTAL ORGANIZATION SAMPLE LETTER OF AGREEMENT

**XXXXXXXX [Name of CE Provider]
LETTER OF AGREEMENT FOR COMMERCIAL SUPPORT OF
CONTINUING EDUCATION ACTIVITIES**

Pursuant to our discussions, this letter is submitted as a formal agreement entered into this ____ day of _____ [month], _____[year] between _____, herein after referred to as "Commercial Supporter", and the XXXXXXXX, herein after referred to as "Provider" for _____ [commercial support, social event support, speaker support] at the Provider's _____ [name of CE activity or activities].

I. Commercial Supporter Responsibilities

Commercial supporter agrees to provide _____ [dollar amount/description of materials to be supplied or other type of support] to support Provider's _____ [name of CE activity] by _____ [date for receipt of funds].

The commercial supporter acknowledges by signature on this letter that it has read the attached XXXXXXXX Guidelines for Commercial Support and will abide by the provisions therein.

II. Provider Responsibilities

For the continuing education activity or activities named above the Provider agrees to: Acknowledge support received from Commercial Supporter in publicity materials for the activity, handout materials, and other Provider communications to its members and CE activity participants as determined by the Provider, provided that support is received in a timely manner so that acknowledgment may be included in such materials. Acknowledgement of commercial support will be value neutral and not an advertisement for the Commercial Supporter or a product.

III. Joint Agreements

It is understood and agreed by both the Provider and Commercial Supporter that:

- A. No formal endorsement shall be stated or implied by the Commercial Supporter for any service as a result of this commercial support.
- B. The Provider shall have total control over any and all decisions pertaining to the seminars, including how many will be given, where they will be located, who will speak, etc.
- C. The seminar materials prepared for use in the seminars is the property of the Provider or the speakers, which have all rights to these materials and their copyrights.

By:

[Commercial Supporter]

[CE Provider]

Signature
[Name]
[Title]

Signature
[Name]
[Title]

Date

Date

COMMERCIAL ORGANIZATION SAMPLE LETTER OF AGREEMENT

**XXXXXXXX [Name of CE Provider]
LETTER OF AGREEMENT FOR COMMERCIAL SUPPORT OF
CONTINUING EDUCATION ACTIVITIES**

_____, hereinafter referred to as Supporter, and XXXXXXXX, hereinafter referred to as Provider, agree that the continuing education activity _____, to be held _____ [dates] in _____ [location] is for educational purposes and not for the purpose of promoting any product, and that any discussion of _____'s product(s) or services will be objective, balanced, and scientifically rigorous.

Supporter and XXXXXXXX further agree that XXXXXXXX will retain and is responsible for exercising full control over the planning of the program's content, including selection of presenters or authors. Supporter agrees not to direct or influence the content of the program nor to play any role in the selection of presenter(s) other than to suggest possible presenters or sources for presenters. If Supporter does suggest possible presenters, such suggestion shall be conveyed to XXXXXXXX in writing and shall include the names of more than one presenter and shall disclose all known significant financial and other relationships between Supporter and the suggested presenters. XXXXXXXX agrees to seek suggestions for presenters from sources other than Supporter to make an independent judgment as to the most appropriate presenter(s), and to select presenter(s) representing an appropriate diversity of legitimate medical/pharmaceutical opinion on the topic being discussed. If XXXXXXXX selects a presenter suggested by Supporter XXXXXXXX agrees to disclose that fact to program participants at the beginning of the program.

XXXXXXXX agrees to ensure meaningful disclosure to the audience or readership of:

- a. Supporter 's funding of the program,
- b. any significant relationship between XXXXXXXX and Supporter and between presenters and Supporter (e.g., employee, grant recipient, owner of significant interest or stock).

Supporter agrees not to engage in scripting, targeting of points for emphasis, or other activities that are designed to influence the content of the program.

XXXXXXXX agrees that, when a product or service marketed by Supporter or a product/service that is in competition with such products/services, is to be the subject of substantial discussion, XXXXXXXX will take steps to ensure that the data will be objectively selected and presented, that both favorable and unfavorable information about the product/service will be fairly represented, and that there is a balanced discussion of the prevailing body of scientific information on the product/service and of reasonable, alternative treatment options.

XXXXXXXX agrees that there will be meaningful disclosure of any limitations on information that is presented. Such limitations or uncertainty include, but are not limited to, data that represent ongoing research, interim analyses, preliminary data, or unsupported opinion.

XXXXXXXX agrees that if unapproved (unlabeled) uses are discussed, the provider will require that presenters disclose that the product is not approved in the United States for the use under discussion.

By:

[Commercial Supporter]

[CE Provider]

Signature
[Name, Title]

Signature
[Name, Title]

Date

Date

DENTAL SCHOOL SAMPLE LETTER OF AGREEMENT

XXXXXXXX [Name of CE Provider]
LETTER OF AGREEMENT FOR COMMERCIAL SUPPORT OF CONTINUING EDUCATION
ACTIVITIES

Regarding Terms, Conditions and Purposes of an Educational Grant between XXXXXX School of Dentistry's Department of Continuing Education and _____ (Insert name of company)

Title of Activity: _____

Location: _____ Date(s) _____

Commercial Supporter (Company Name/Branch): _____

Contact Person: _____

Title: _____

Address: _____

Telephone: _____ Fax: _____ E-mail: _____

The above company wishes to provide support for the named continuing education activity by means of (indicate which option):

1. Unrestricted educational grant for support of this activity in the amount of: \$ _____

2. Restricted grant to reimburse expenses for:

A. Speaker(s)

(1) _____

(2) _____

B. To include:

All Expenses ____ Travel Only ____ Honorarium Only _____

Honorarium Amount(s)

(to be determined by Course Director) \$ _____

C. Support for catering functions (specify)

In the amount of; \$ _____

D. Other (e.g., donation or loan of equipment, supplies, etc.)

CONDITIONS

1. Statement of Purpose: program is for scientific and educational purposes only and will not promote the company's products, directly or indirectly.
2. Control of Content & Selection of Presenters & Moderators: XXXXXXXX is responsible for control of content and selection of presenters and moderators. The Company agrees not to direct the content of the program. The Company, or its agents, will respond only to XXXXXXXX initiated requests for suggestions of presenters or sources of possible presenters. The Company will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Company and speaker, and will provide this information in writing. XXXXXXXX will record role of Company, or its agents, in suggesting presenter(s); will seek suggestions from other sources, and will make selection of presenter(s) based on balance and independence.

3. Disclosure of Financial Relationships: XXXXXXXX will ensure meaningful disclosure to the audience at the time of the program, of (a) Company funding and (b) any significant relationship between XXXXXXXX and the Company (e.g., grant recipient) or between individual speakers or moderators and the Company.
4. Involvement in Content: there will be no "scripting", emphasis, or direction of content by the Company or its agents.
5. Ancillary Promotional Activities: no promotional activities will be permitted in the same room or obligate path as the educational activity. No product advertisements will be permitted in the program room.
6. Objectivity & Balance: XXXXXXXX will make every effort to ensure that data regarding the company's products (or competing products) are objectively selected and presented, with favorable and unfavorable information and balanced discussion of prevailing information in the product(s) and/or alternative treatments.
7. Limitations on Data: XXXXXXXX will ensure, to the extent possible, meaningful disclosure of limitations on data, e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion.
8. Discussion of Unapproved Uses: XXXXXXXX will require that presenters disclose when a product is not approved in the United States for the use under discussion.
9. Opportunities for Debate: XXXXXXXX will ensure meaningful opportunities for questioning or scientific debate.
10. Independence of XXXXXXXX in the use of Contributed Funds: a. funds are to be in the form of an educational grant made payable to of Dentistry Continuing Education; b. all other support associated with this CE activity (e.g., distributing brochures, preparing slides, etc.) must be given with the full knowledge and approval of XXXXXXXX; c. no other funds from the company will be paid to the program director, lecturer/author, or others involved with the activity (additional honoraria, extra social events, etc.).

The Commercial Supporter agrees to abide by all the requirements of the Standards for Commercial Support of Continuing Education for Health Professionals.

XXXXXXX agrees to: 1) abide by the Standards for Commercial Support of Continuing Education for Health Professionals, 2) acknowledge educational support from the commercial company in program brochures, syllabi, and other program materials, and 3) upon request, furnish the commercial supporter a report concerning the expenditure of the funds provided.

AGREED

Commercial Supporter (Insert name of company)

Commercial Supporter Representative: _____

(Insert name of representative)

Signature: _____ Date: _____

Dental School (Insert name of institution)

XXXXXXX CE Director: _____ Dept. _____

(Insert name of director)

Signature: _____ Date: _____

SAMPLE

[Name of CE Provider]

CONFLICT OF INTEREST DECLARATION

A conflict of interest may be considered to exist if a continuing dental education speaker is affiliated with, or has a financial interest in any organization(s) that may be co-supporting a course or may have a direct interest in the subject matter of the presentation. The intent of this policy is not to prevent a speaker with an affiliation or financial interest from making a presentation. It is intended that any potential conflict be identified openly so that the attendees have the full disclosure of the facts and may form their own judgments about the presentation.

DECLARATION

I, the undersigned, declare that neither I nor any member of my family have a financial arrangement or affiliation with any corporate organization offering financial support or grant monies for this continuing dental education program, nor do I have a financial interest in any commercial product(s) or service(s) I will discuss in the presentation.

Name

Signature/ Date

I, the undersigned, (or an immediate family member), have a financial interest/arrangement or affiliation with the corporate organization offering financial support or grant monies for this continuing dental education program, or I do have a financial interest in any commercial product(s) or services I will discuss in the presentation.

Having an interest in or an affiliation with a corporate organization does not necessarily prevent you from making a presentation, but the relationship must be made known to the audience. Failure to disclose or a false disclosure will require (Provider Name) to remove you from the program and to identify a replacement for your participation.

Affiliation/Financial Interest

Corporate Organization

Grants/Research Support	_____
Consultant	_____
Stock Shareholder	_____
Honorarium	_____
Other Financial or Material Support	_____

Name

Signature /Date

NATIONAL DENTAL ORGANIZATION SAMPLE

[Name of CE Provider]

CONFLICT OF INTEREST DECLARATION

It is the policy of the XXXXXXXX that all practice-related speakers at any program sponsored by the XXXXXXXX shall complete a conflict of interest statement regarding any interest in a company or a product related to the program as a part of the Speaker's Agreement with the XXXXXXXX. Further, any portion of the following information can be shared with the membership and/or attendees to gain perspective of the program.

In accordance with this policy, I, _____ declare that I have no proprietary, financial or other personal interest of any nature or kind in any product, service and/or company that will be discussed or considered during the proposed program, except the following:

I declare that I have no proprietary financial or other personal interest of any nature or kind in any firm beneficially associated with any product and/or service that will be discussed or considered during the proposed program, except the following:

I declare that I have no past or present financial interest, consulting position or other involvement of any nature or kind related to the program that could give rise to even a suspicion of a conflict of interest, except the following:

Furthermore, I understand and agree that as a condition for participating as a speaker at an XXXXXXXX sponsored program, I will exercise particular care that no detriment to the XXXXXXXX will result from conflicts between my interests and those of the XXXXXXXX.

Having read and understood the XXXXXXXX policy and having completed this statement to the best of my knowledge and belief, I agree to be bound by the terms hereof.

Signature/Date