

<b>Subject:</b> Business Ethics	<b>Policy Number:</b> BE-005
<b>Policy:</b> Training and Education	<b>Effective Date:</b> July 1, 2016
	<b>Revision</b> <b>Date(s):</b>

- I. General Policy.** Clinical Innovations may provide Training and Education to Customers to facilitate the safe and effective use of Clinical Innovations Devices. Clinical Innovations shall provide Training and Education in accordance with this Policy and applicable laws, regulations and industry guidelines, including all FDA requirements on product promotion.
- II. Specific Policies.**
- A. Training and Education.** Training and Education may be provided to Customers under the following circumstances:
1. Except for In-Service Training, Training and Education programs and events must be individually reviewed and approved by the CMO prior to the Training and Education program or event.
  2. In order to facilitate safe and effective use of Clinical Innovations Devices, Training and Education programs and Training Materials shall be made available to all Customers who use or have purchased, leased, or ordered Clinical Innovations Devices.
  3. The content of Training and Education programs and Training Materials is subject to evaluation in accordance with all Clinical Innovations policies on the review and approval of advertising and promotion prior to use. No Training and Education program or Training Material shall be approved unless the following conditions are met:
    - a. Training and Education programs shall focus on the safe and effective use of Clinical Innovations Devices or information directly concerning or associated with the manufacturing or use of Clinical Innovations Devices (e.g., plant tour; presentation about disease states and the benefits of Devices to certain patient populations).
    - b. Training and Education programs and Training Material disseminated for a Device shall be consistent with the Approved Use and directions for use (i.e., on-label) and consistent with all other FDA rules applicable to Clinical Innovations.
    - c. Training Material that provides summary, abbreviated or otherwise incomplete directions for use shall refer users to the full directions for use.

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4. Sales personnel may provide input on Training and Education programs and Training Materials, but shall not determine the content of Training and Education programs or Training Materials.
5. Training and Education programs shall be conducted in settings that are conducive to the effective transmission of knowledge by individuals having the necessary qualifications and experience to effectively convey scientific and practice information.
6. Training and Education requiring “hands on” training shall be held at appropriate facilities and facility staff should have the proper qualifications and expertise to conduct such training.
7. When objective reasons support the need for out-of-town travel to efficiently deliver a Training and Education program, Clinical Innovations may pay for reasonable travel and modest lodging costs for attending Customers. It is allowable to extend the date of travel only if the extension results an overall reduced expense for Clinical Innovations (e.g. a Saturday evening stay results in an overall reduced expense due to less expensive airfare on Sunday even when factoring in the extra night of lodging and meals directly occasioned by the extended stay). Clinical Innovations may pay for additional meals and lodging directly occasioned by the extended stay, but additional meals and lodging beyond the extension are not coverable by Clinical Innovations under these circumstances and must not be reimbursed.
8. Meals provided in conjunction with Training and Education programs shall be in accordance with the Business Courtesy Meals Policy (BE-001).
9. It is never appropriate for Clinical Innovations to compensate Customers for their time to attend Training and Education or to pay for expenses incurred by any person who does not have a bona fide professional interest in the information being provided (e.g., spouse or other guest).
10. Clinical Innovations shall not provide recreation or entertainment in conjunction with Training and Education programs.
11. Clinical Innovations shall ensure attendees are aware that Training and Education Programs are company-organized.
12. Speakers shall disclose conflicts of interest.

### **III. Prohibited Training and Education.**

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- A. Clinical Innovations shall not offer Training and Education that provide significant independent value to a Customer by eliminating an expense that otherwise would have been incurred.
  - B. Clinical Innovations shall not provide Training and Education for Unapproved Devices or Unapproved Uses except as permitted under FDA guidance. If a Customer asks whether Training and Education will be provided for patients treated for conditions outside the conditions described in the Food and Drug Administration (FDA) Approved Labeling, the sales representative shall refer the Customer to Clinical Innovations' CMO.
- IV. Documentation.** Clinical Innovations maintains records of all payments made and benefits provided in connection with Training and Education programs. A detailed expense report with supporting documentation is required. All expenses must be reported via the Clinical Innovations employee expense report system. (Note: Distributor representatives should report on their standard expense report form.)
- V. Additional Restrictions and Disclosure Requirements.** A number of states and foreign countries impose additional restrictions on Clinical Innovations' activities and its interactions with Customers. In addition, the federal government and some states require tracking or disclosure of economic benefits associated with certain activities and interactions. The standards for federal disclosure of economic benefits are set forth in the Disclosure of Certain Payments and Other Transfers of Value Policy (BE-008). Clinical Innovations Personnel are responsible for complying with state-specific requirements, some of which are referenced in BE-008.