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Subject: Business Ethics	**Effective Date: July 1, 2016**
Policy: Grants; Donations	**Revision Date(s):**

I. General Policy. Clinical Innovations may provide Grants to support bona fide Educational Activities, including but not limited to conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by a Customer that is an accredited continuing medical education provider. Clinical Innovations may also provide Grants to support bona fide scientific research conducted by qualified Grant recipients and Donations to charitable entities for bona fide charitable purposes. Grants and Donations may be provided in accordance with this Policy and applicable laws, regulations and industry guidelines.

II. Specific Policies.

A. Permissible Educational Grants. Clinical Innovations may provide Grants to conference sponsors or training intuitions for legitimate purposes, including but not limited to, the advancement of medical education, or in support of public education under the following circumstances:

1. The conference sponsor or training institution agrees to adhere to all rules associated with any accreditation of the program;

2. The conference or training is primarily dedicated to promoting discourse that is objective and scientifically rigorous;

3. The conference or training provides medical, scientific or health-related education in areas of relevance to Clinical Innovations;

4. The recipient of the Grant retains control over all aspects of the conference or training, including the structure, content, speakers, selection of attendees or scholarship recipients, and distribution of educational materials (although Clinical Innovations representatives may provide input regarding suitable speakers if requested to do so by the conference organizer);

5. If the Grant is for a conference, use of the funds is (i) to reduce overall costs, (ii) for reasonable honoraria, lodging, travel and meals for healthcare professionals who are bona fide conference faculty members at the conference, (iii) for modest meals at the conference when done so in accordance with the Business Courtesy Meals Policy (BE-001) or (iv) for scholarships to reduce attendance costs for residents, fellows, and other health care professionals in training that are consistent with this policy; and

6. If the Grant is to support a program sponsored by a Customer, the program does not supply credit required for an academic degree for that Customer's

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own students or underwrite an expense that the Customer would normally incur in the course of its business, with the following exceptions:

a. occasional support of "grand rounds" in dollar amounts not to exceed $125 per event used for the periodic education of the Customer's own students provided that the Customer routinely solicits all competing vendors for support; and

b. Donation of product to be used in a clinical training event.

B. Permissible Research Grants. Clinical Innovations may fund legitimate, scientifically rigorous clinical and preclinical research in areas of relevance to Clinical Innovations where such research is conducted by qualified Grant recipients and is intended to provide valuable scientific and clinical information, improve clinical care, provide leads to promising new treatments, promote better delivery of health care, or provide other benefits to patients.

1. Clinical Innovations Devices may be provided free of charge for use in research supported by the research Grant, provided that neither the Grant recipient nor any investigator may bill any study subject or any third party for such Device.

C. Permissible Donations. Clinical Innovations may provide a Donation to advance a bona fide charitable purpose only if the Donation recipient enjoys tax-exempt status as a public charity under section 501(c)(3) of the Internal Revenue Code, or as a state instrumentality under Section 170(c)(1) of the Internal Revenue Code or the recipient is an HCP serving a charitable mission in a third-world country;

D. Prohibited Grants and Donations.

1. Except as provided in this Policy, Grants and Donations shall not be provided:

a. to any individual (excepting Donations to HCPs serving a bona fide charitable mission) or to defray the expenses of a specific individual;

b. at the request of a Customer;

c. to support the acquisition of equipment or provide general operational support for a Customer; or

d. to support consulting or other services to Clinical Innovations, which are governed by the Consulting Policy (BE-004).

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2. Grants and Donations shall not be offered or provided with the intent of, directly or indirectly, implicitly or explicitly influencing or encouraging the recipient to use, purchase, lease, order, or arrange for or recommend the use, purchase, lease, or order of Clinical Innovations Devices or as a reward for past such behavior or for any other improper purpose.

E. Requests for Grants and Donations.

1. All requests for Grants and Donations shall be independently initiated in writing by the entity that would receive the Grant or Donation. When a Clinical Innovations sales representative is asked about Clinical Innovations' Grants or donations, they should inform the requestor that Clinical Innovations has a Grant/Donation process and how to access the program information but should not say or do anything to suggest that the sales representative can control or influence the Grant or Donation and should not help prepare or deliver the request.

2. All requests for Grants and Donations shall set forth: (a) a description of the intended use of the funds; (b) an explanation of how the proposed Grant or Donation is consistent with Clinical Innovations' mission or disease areas of interest; (c) for Grants, a detailed budget showing how the Grant funds would be spent; (d) the requestor's name, address and federal tax identification number; (e) name, address and qualifications (e.g., curriculum vitae) of the individual(s) who would conduct the research, if applicable; and (f) evidence of the charitable tax-exempt status of the charitable entity, if applicable.

3. A Grant or Donation request should be submitted with all required documentation in one of the following three ways:

a. Email all documents to the Clinical Innovations Chief Medical Officer ("CMO").

b. Fax all documentation to 801-266-7373 to the attention of the Clinical Innovations CMO.

c. Mail all documentation to the following addressing:

Clinical Innovations LLC
Attn: Chief Medical Officer
747 W 4170 S
Salt Lake City, UT 84123
801-268-8200 (Phone)

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F. Approval of Grants and Donations.

1. All Grant and Donation requests shall be reviewed by a review committee that shall maintain a record of the determination whether to approve or reject the request that includes a certification that the committee considered each of the criteria set forth in this Section F as appropriate for the type of request.

a. The review committee shall consist of the chair (the CMO) and representatives from each of the following departments: (i) Executive; (ii) Finance; (iii) Regulatory; and (iv) Research & Development.

b. Clinical Innovations sales personnel may provide input about the suitability of a proposed Grant or Donation recipient or Educational Activities, but shall not promote particular applications for support nor control or otherwise attempt to influence funding decisions. Sales personnel shall not be on the review committee, be involved in the solicitation of Grant or Donation requests or otherwise assist in the preparation, review, or evaluation of requests for support. Clinical Innovations sales personnel may not hand-deliver checks when funding is approved.

2. In evaluating the merits of a particular request for a Grant or Donation, the reviewers on the review committee shall consider the following factors:

a. the purpose to be served by the Grant or Donation, including the manner in which the Grant or Donation will be used, the underlying patient care benefit, and the extent to which the Grant or Donation will further Clinical Innovations' mission or provide education regarding disease areas or conditions of interest to Clinical Innovations as determined in accordance with the Clinical Innovations' Needs Assessment Policy (BE-006);

b. whether the Grant or Donation is consistent with FDA requirements regarding Unapproved Devices and Unapproved Uses;

c. the quality of the Educational Activities or research proposal, including whether the activities are likely to produce meaningful information not otherwise available;

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d. whether the amount of the Grant or Donation request is reasonable and justified;

e. the mix of other Educational Activities, research, or charitable entities currently receiving funding from Clinical Innovations;

f. the reputation and expertise of the Grant or Donation recipient, including for research Grants, the qualifications and expertise of the proposed researcher;

g. the performance of the Grant recipient under previous Grant agreements, if any; and

h. any other criteria deemed appropriate.

G. Award of Grants and Donations.

1. Grants. All Grant agreements shall include the provisions contained in Attachment BE-003 or suitable alternative provisions that may be approved in consultation with the Compliance Officer or legal counsel as appropriate.

a. Research Grants. In addition to the provisions contained in Attachment BE-003, agreements pertaining to research Grants shall also include the following terms:

i. if the research is to be conducted over more than one year, the schedule of support and reporting and performance conditions for continued funding past the first budget year;

ii. obligation for the research to provide Clinical Innovations periodic reports on the progress and findings of the research, including, at a minimum, submission of annual progress reports and a written report, or equivalent documentation of the work that has been done, upon conclusion of the research;

iii. prohibition on billing any study subject or any third party for product provided free of charge by Clinical Innovations, if any; and

iv. obligation for Grant recipient to comply with all applicable statutory, regulation and other requirements associated with the research activities, including but not limited to:

compliance with investigational device exemption requirements under 21 C.F.R. Part 812; requirements for the protection of human subjects under 45 C.F.R. Part 46; all clinical trial registration requirements including those at 42 U.S.C. § 2820 that have been expanded to include medical device trials in accordance with Title VIII of U.S. Public Law 110-85, otherwise known as the Food and Drug Administration Amendments Act of 2007; and, for any Grant used to conduct research for on-label studies of approved devices, adverse event reporting requirements under 21 C.F.R. Part 803.

2. **Oversight of Research Grants.** The CMO and/or Research & Development shall oversee the execution of Grant research with the goal of assuring that all Grant support is used consistent with the terms of the Grant agreement.

3. **Donations.** A Donation award letter, in a form that may be approved in consultation with the Compliance Officer or legal counsel as appropriate shall be provided to the charitable entity prior to or with the Donation.

4. **No Return on Investment Analyses.** Return on investment analyses and other tracking for the purpose of business generation shall not be conducted in connection with Grants or Donations.

H. **Clinical Innovations Representatives at Educational Activities**.

1. Clinical Innovations Personnel may attend Educational Activities to the extent permitted by the rules or procedures of Grant recipient and accreditation of the program (if any), including rules that prohibit promotion of products or discussion of such products with HCPs in the educational space or place of the medical education program immediately before, during or after a medical education activity. Clinical Innovations Personnel shall not participate proactively in program discussions, or ask questions during the program.

2. Clinical Innovations may pay for exhibit space and advertising at educational events or other events that will reach an audience interested in Clinical Innovations products as long as payments are fair market value.

I. **Governmental Personnel.** No Grants or Donations shall be provided to or to support the activities of any Federal, state, local or other government entities or personnel (including, for example, employees of state, county, or city facilities)

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without prior approval of the Compliance Officer or legal counsel as appropriate to determine consistency with the laws governing economic benefits to such entities and individuals.

III. Documentation. Before the Grant agreement or Donation letter is executed or payment is issued to the Grant or Donation recipient, the Clinical Innovations employee responsible for providing the Grant or Donation is responsible for maintaining and supplying to the Finance Department:

A. Grant or Donation request materials;

B. Documentation of the outcome of the committee review;

C. Grant agreement or Donation letter for each approved Grant or Donation;

D. Records of all support provided by Clinical Innovations in connection with the Grant or Donation;

E. For research Grants, all reports submitted pursuant to the Grant agreement; and

F. For in-kind support (i.e., Donation of a Device), documentation of how the product will be used in a charitable manner.

IV. 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.

ATTACHMENT BE-003

Note: While suitable for educational Grants, research Grants for investigator-initiated studies typically have more provisions dealing with issues such as intellectual property, indemnity, performance.

Clinical Innovations Letter Agreement

[Educational] [Research] Grant

Dear **[Grant Recipient]**:

We are pleased to advise you that the Clinical Innovations, LLC ("CI") has approved your request for an [Educational] [Research] Grant ("Grant"). CI will provide **[Grant Recipient]** (the ["Educational Provider"] ["Researcher"]) with a Grant in the amount of $_____ ("Grant Funds"), subject to the return of a signed copy of this letter.

This Grant is to be used exclusively to fund expenses directly related to the [educational] [research] program ("Program") described in your request [and the research protocol] and is subject to the following requirements govern this Grant.

1. **Scope and Presentation of Program Activities**: The Program is for scientific and/or educational purposes only and will not promote, directly or indirectly, any product developed, marketed or manufactured by CI. [The Educational Provider will make every effort to ensure that the Program is free from commercial bias for or against any product and that any presentation of information about CI's products (or competing products) is an objective and balanced discussion of prevailing information about the product(s) and alternative treatments. Where reasonably practical based on the program format, the Educational Provider will ensure meaningful opportunities for questioning or scientific debate.]

2. **Funding Intent**: The parties acknowledge and agree that this Grant is intended to provide support consistent with federal and state laws and regulations and is not (a) a price concession, (b) contingent on the purchase or recommendation of any CI products, (c) intended to induce [Educational Provider] [Researcher] to prescribe, purchase or recommend CI products) or (d) compensation for the past or future prescription, purchase or recommendation of CI products.

3. [**Control of Program Planning, Content, Evaluation and Fund Disbursement**: Educational Provider is solely responsible for the planning, content, conduct, quality, scientific integrity, implementation, promotion, evaluation, selection of presenters and moderators, and selection of planning committee members, or other persons and organizations that will be in a position to control Program content.]

4. [**Involvement in Content**: CI shall not engage in scripting, targeting points for emphasis, or other actions designed to influence the content of the Program. Neither CI nor its agents may disseminate information about the Program (*e.g.*, invitations, brochures) other than at the unsolicited written request of the Educational Provider.]

5. **Disclosure of Financial and Other Relationships**: The [Educational Provider] [Researcher] will ensure meaningful disclosure [to the audience, at the start of the program and] in Program publications, of (a) CI's funding, without reference to specific products or trade names, (b) any relevant financial or other significant relationship with CI, [(c) any relevant financial or other relationship between CI and individual presenters or moderators, planning committee members, or other persons and organizations that are in a position to control Program content that may give rise to a conflict of interest. In addition, the Educational Provider will acknowledge educational support from CI in invitations, brochures, syllabi, and other Program materials.]

6. [**Disclosure of Other Information**: The Educational Provider will disclose when a product is not approved in the United States for the use under discussion. The Educational Provider will ensure, to the extent possible, meaningful disclosure by presenters and moderators of limitations on data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion).]

7. [**Ancillary Promotional Activities**: Promotional activities and product advertisements are not permitted in the educational space immediately before, during, or after the Program. Print advertisements will not be interleafed or distributed with Program educational materials.]

8. **Use of Grant Funds**: The [Educational Provider] [Researcher] will use Grant Funds exclusively for the purposes identified in the Grant request. Upon request, the [Educational Provider] [Researcher] will furnish CI with records of the manner in which the Grant Funds were expended. Any portion of the Grant Funds remaining after the Program will be returned to CI.

9. **Applicable Law and Standards**: The [Educational Provider] [Researcher] agrees to abide by applicable state and federal laws, regulations and policies, [[ed Grant] including the Food and Drug Administration's Guidance for Industry: Industry-Supported Scientific and Educational Activities (Nov. 1997), and the Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers (2003), and, where applicable, policies of the Accreditation Council for Continuing Medical Education ("ACCME"), including ACCME Standards for Commercial Support of Continuing Medical Education] [res Grant] generally accepted standards of good clinical practice, and all applicable local, federal and state laws and regulations governing performance of the Research, including without limitation the Health Insurance Portability and Accountability Act ("HIPAA") and the Food, Drug and Cosmetic Act and their implementing regulations as well as IRB approval if applicable].

Your return of a signed copy of this letter will acknowledge that the obligations set out above are effective and binding.

Sincerely,

[Signature]
[Name]
[Title]

AGREED

Grant Recipient Representative (type/print name): _____

Signature: _____ Date: _____

Please return this form in the enclosed addressed and stamped envelope. Once the signed document is received, we will complete the payment process and _____.