| | |
|---|---|
| | **Policy Number: BE-004** |
| **Subject: Business Ethics** | **Effective Date: July 1, 2016** |
| **Policy: Consulting** | **Revision Date(s):** |

**I. General Policy.** Clinical Innovations may engage Customers to perform bona fide consulting services, such as research, product development, participation on advisory boards, speaking and presentations at training or educational programs, for which Clinical Innovations has a legitimate business need and in compliance with this Policy and applicable laws, regulations and industry guidelines.

**II. Specific Policies**.

**A. Consulting Arrangements.** Consulting arrangements may be entered into only if all of the following conditions have been met:

**1.** A legitimate need for the services has been clearly identified and documented in advance as determined in accordance with Clinical Innovations' Needs Assessment Policy (BE-006).

**2.** A written Consulting Agreement (in a form that may be approved in consultation with the Compliance Officer or legal counsel as appropriate) that meets the standards set forth in this Policy is signed by all of the parties prior to the start of the services and prior to payment.

**3.** The number of consultants retained is not greater than the number reasonably necessary to achieve the identified need.

**4.** The criteria for selecting consultants, including their education, expertise and competency to perform the required task, are directly related to the identified need and not related to the volume or value of Clinical Innovations Devices used, ordered, purchased, leased or recommended by the individual. To this end:

**a.** persons responsible for selecting the consultants shall have the expertise necessary to evaluate whether the consultant meets the established criteria; and

**b.** sales personnel may provide input about the suitability of a proposed consultant, but shall not control or influence the decision of whether to engage a particular Customer as a consultant.

**5.** The services are not 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 or for any other improper purpose.

| | | |
|---|---|---|
| | | **Policy Number: BE-004** |
| **Subject:** | **Business Ethics** | **Effective Date: July 1, 2016** |
| **Policy:** | **Consulting** | **Revision Date(s):** |

**B. Consultant Meetings**.

**1.** Consulting meetings are intended to be used to receive information, advice or feedback from participating consultants on matters of importance to Clinical Innovations as reflected in meeting agendas. Consulting meetings shall not be used as opportunities to sell, market, or promote or merely provide information or data to the consultants.

**2.** Clinical Innovations shall share information with consultants to the extent necessary for the consultants to perform their services. Information about Unapproved Devices and Unapproved Uses shall be carefully tailored to the legitimate objectives of the meeting and the desired feedback in accordance with FDA requirements regarding the promotion of Unapproved Devices and Unapproved Uses.

**3.** The number of consultants at a meeting and the number of consultant meetings (with the same or different consultants) shall not exceed what is needed to reasonably achieve legitimate Clinical Innovations objectives. If the same questions are addressed in, or the same group of consultants attends, multiple consulting meetings, the documentation supporting the legitimate business need must reflect why such meetings are necessary and not duplicative.

**4.** Consulting meetings shall occur in a clinical, educational, or conference setting or another venue conducive to the effective exchange of information and shall be designed to ensure active participation from all attendees. The process for collecting, analyzing, and incorporating advice from consultants shall be formally documented and Clinical Innovations shall keep a record of advice provided by consultants and of how the advice is used (or why it is not).

**C. Speakers and Speaker Training**.

**1.** Consultants must receive speaker training regarding Clinical Innovations Compliance Policies. Consultants should also receive training on the Food and Drug Administration (FDA) rules regarding advertising and promotion if there is a reasonable basis to believe the Device may be used off-label. Such training(s) must take place before the Consultants can make presentations on behalf of Clinical Innovations.

**2.** A consultant who is acting as a paid speaker for Clinical Innovations shall clearly identify that Clinical Innovations is sponsoring his or her presentation and disclose to the audience that the consultant is presenting

| | | |
|---|---|---|
| | | **Policy Number: BE-004** |
| **Subject:** | **Business Ethics** | **Effective Date: July 1, 2016** |
| **Policy:** | **Consulting** | **Revision Date(s):** |

on behalf of Clinical Innovations. Consultant presentations on behalf of Clinical Innovations must be consistent with Approved Use and directions for use (i.e., on-label) and consistent with all other FDA rules applicable to Clinical Innovations.

**D. Consulting Agreement.** Agreements with Customers for the provision of consulting services shall be for a minimum of one year (or if for less than one year, the terms of which may not be renegotiated within a one-year period) and must specify in detail:

**1.** the services to be provided, including the study protocol if the agreement is for research services;

**2.** the term of the agreement;

**3.** the basis for payment;

**4.** any obligation for Clinical Innovations to provide meals and/or reimburse for travel and lodging expenses that are necessary to carry out the consulting arrangement; and

**5.** adequate assurance that the Consultant Agreement is consistent with consultant's other contractual and employment obligations, including requiring all appropriate disclosures.

**E. Compensation and Royalties**.

**1. Compensation.**

**a.** Compensation under a consultant's agreement shall not exceed the fair market value of the services being performed based upon the time spent on services, shall not vary based upon the volume or value of a consultant's past, present, or anticipated business, and may not be extended to the consultant as a reward for prior business or as an inducement for future business.

**b.** Compensation shall not be paid to ensure a consultant's "availability" (e.g., no retainer agreements).

**c.** See Attachment BE-004 for current compensation guidelines.

**2. Royalties.** In addition to meeting the other requirements of this Policy, consulting arrangements involving payments of royalties (e.g., Device or

| | | |
|---|---|---|
| | | **Policy Number: BE-004** |
| **Subject:** | **Business Ethics** | **Effective Date: July 1, 2016** |
| **Policy:** | **Consulting** | **Revision Date(s):** |

technology development or intellectual property licensing agreements) shall only be entered into if all of the following conditions have been met:

**a.** The Customer is expected to make or has made a significant, innovative contribution to intellectual property owned by Clinical Innovations (e.g., the development of a Device, technology, process, or method). Such contributions may take the form of patented or copyrighted technology or know-how.

**b.** The basis for compensation shall be appropriately documented.

**c.** The calculation and amount of the royalty shall be based on factors that preserve the objectivity of the recipient's medical decision-making and may not be conditioned on (1) a requirement that the Customer purchase, order or recommend any Clinical Innovations Device or technology produced as a result of the project, or (2) a requirement that the Customer market the Device or technology upon commercialization.

**F. Travel, Lodging and Meal Expenses**.

**1.** Clinical Innovations may pay for reasonable and actual travel, lodging and meal expenses for a consultant that are reasonably necessary in connection with the services being provided. Clinical Innovations may also reimburse a consultant for such expenses if documented and incurred by the consultant.

**2.** Clinical Innovations shall not pay for the travel or other expenses (e.g., the cost of meals) of a spouse or other guest of consultants.

**3.** Clinical Innovations may provide modest business courtesy meals to consultants in conjunction with consultant meetings in accordance with the Business Courtesy Meals Policy (BE-001).

**G. Payment and Reimbursement**.

**1.** No compensation or royalties shall be provided under Consulting Agreements except with pre-existing documentation of verified work performed or intellectual property provided, including a description of the work, amount of time spent, and date of performance. Failure to provide services or applicable documentation may result in termination of Consulting Agreement.

| | | |
|---|---|---|
| | | **Policy Number: BE-004** |
| **Subject:** | **Business Ethics** | **Effective Date: July 1, 2016** |
| **Policy:** | **Consulting** | **Revision Date(s):** |

**2.** No payment shall be made under the Consulting Agreement for travel, lodging or meal expenses permitted under this Policy except as authorized in a Consulting Agreement and verified by Clinical Innovations (e.g., original receipts or other supporting documentation).

**H. Governmental Personnel.** No consulting arrangement may be offered or entered into with any Federal, state, local or other government personnel (including, for example, employees of state, county, or city facilities) without prior approval of the Compliance Officer or legal counsel as appropriate to determine consistency with the laws governing economic benefits to such individuals.

**III. Documentation.** Before the Consulting Agreement is executed or payment is issued under the Consulting Agreement, the Clinical Innovations employee responsible for executing the Consulting Agreement is responsible for maintaining and supplying to the Finance Department:

**A.** Needs assessment supporting the legitimate business need for the consulting arrangement;

**B.** Consulting Agreement;

**C.** Evidence of fair market value of consulting services (which may be physician compensation survey data or individualized report prepared by a qualified person);

**D.** Documentation evidencing the performance of the services under the Consulting Agreement;

**E.** Documentation evidencing the expenses provided or reimbursed by Clinical Innovations under the Consulting Agreement are in connection with services rendered by the consultant; and

**F.** Records of all payments made and benefits provided in connection with the Consulting Agreement.

**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-004

**1.** The fair market value of a consultant's service may be derived from documented industry benchmarks, recognized surveys, or an independent valuation consultant.

**2.** The following guidelines are considered current as of **July 1, 2016:**

**i.** Medical Advisory Board members who are specifically qualified may be compensated up to approximately $150 to $350 or £90 to £275 per hour for specified services delivered. Stock options may not be provided.

**ii.** Physician faculty may be compensated up to approximately $150 to $350 or £90 to £275 per hour for specific services delivered. Stock options may not be provided.