



<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

**A. INTRODUCTION TO THE ADVAMED CODE**

Accuray Incorporated (“Accuray”) recognizes the obligation to facilitate ethical interactions between Accuray employees and those individuals who purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Medical Technologies in the United States (“Health Care Professionals”). All Accuray representatives are expected to follow ethical business practices at all times and respect the obligation of health care professionals to make independent decisions regarding patient care. Consequently, Accuray has implemented this policy (the “Policy”) adopting the Advanced Medical Technology Association (“AdvaMed”) Code of Ethics on Interactions with Health Care Professionals (“Code of Ethics” or “Code”), effective July 1, 2011.

AdvaMed is a U.S. based medical device trade association that represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities (“Medical Technologies”) in order to enable patients to live longer and healthier lives. Because Accuray has made the decision to adopt and comply with the AdvaMed Code, Accuray is considered a member company (referred to in this Code collectively as “Companies,” and individually as “Company”) and has adopted the AdvaMed Code worldwide. This Policy applies to all of Accuray’s interactions with Health Care Professionals globally and all Accuray representatives worldwide are expected to comply with it. If this Policy conflicts with a country’s own regulations and an Accuray representative wants only to comply with such country’s regulations and not this Policy in a limited circumstance, he or she may seek a written exception to compliance with this Policy from any of the Corporate Compliance Officers (as defined below). Please note that generally speaking, and outside of any such written approval, in the event that local regulations regarding interactions with Health Care Professionals exist, in addition to this Policy, Accuray representatives are expected to follow the most stringent among them.

The scope of beneficial interactions between Health Care Professionals and Companies is broad and includes interactions intended to:

- *Promote the Advancement of Medical Technologies.* Developing and improving cutting edge Medical Technologies are collaborative processes between Companies and Health Care Professionals, Innovation and creativity are essential to the development and evolution of Medical Technologies, which often occur outside a Company’s laboratory.

<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

- *Enhance the Safe and Effective Use of Medical Technologies.* The safe and effective use of sophisticated electronic, *in vitro* diagnostic, surgical, or other Medical Technologies often requires Companies to provide Health Care Professionals appropriate instruction, education, training, service and technical support. Regulators often require this type of training as a condition of product approval.
- *Encourage Research and Education.* Companies' support of *bona fide* medical research, education, and enhancement of professional skills improves patient safety and increases access to Medical Technologies.
- *Foster Charitable Donations and Giving.* Companies make monetary and Medical Technology donations for charitable purposes, such as supporting indigent care, as well as patient and public education. This increases access to—as well as the quality of—care and treatment in patient populations that may not otherwise be reached.

## **B. CODE OF ETHICS COMPLIANCE**

Accuray's General Counsel and Chief Financial Officer (the "Corporate Compliance Officers") are responsible for the enforcement of this Code.

This Code is a part of and is enforced by Accuray's Corporate Compliance Program. As applied to this Code, Accuray's Corporate Compliance Program consists of the following elements: (1) implementing written policies and procedures; (2) designating a compliance officer; (3) conducting effective training and education; (4) developing effective lines of communication (including an anonymous reporting function); (5) conducting internal monitoring and auditing; (6) enforcing standards through well-publicized disciplinary guidelines; and (7) responding promptly to detected problems and undertaking corrective action.

## **C. COMPANY-CONDUCTED PRODUCT TRAINING AND EDUCATION**

Companies have a responsibility to make training and education on their products and Medical Technologies available to Health Care Professionals. Companies may also provide education to Health Care Professionals. "Training" means training on the safe and effective use of Medical Technologies. "Education" means communicating information directly concerning or associated with the use of Companies' Medical Technologies, e.g., information about disease states and the benefits of Medical



<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

Technologies to certain patient populations. Training and Education programs include, but are not limited to, “hands on” training sessions, cadaver workshops, lectures and presentations, and grand rounds. In fact, the U.S. Food and Drug Administration mandates training and education to facilitate the safe and effective use of certain Medical Technologies. Companies should adhere to the following principles when conducting training and education programs concerning Medical Technologies for Health Care Professionals:

- Programs and events should be conducted in settings that are conducive to the effective transmission of information. These may include clinical, educational, conference, or other settings, such as hotels or other commercially available meeting facilities. In some cases, it may be appropriate for a Company representative to provide training and education at the Health Care Professional’s location.
- Programs providing “hands on” training on Medical Technologies should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff used by the Company should have the proper qualifications and expertise to conduct such training. Training staff may include qualified field sales employees who have the technical expertise necessary to perform the training.
- Companies may provide Health Care Professional attendees with modest meals and refreshments in connection with these programs. Any such meals and refreshments should be modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting.
- Where there are objective reasons to support the need for out-of-town travel to efficiently deliver Training and Education on Medical Technologies, Companies may pay for reasonable travel and modest lodging costs of the attending Health Care Professionals. It is not appropriate for Companies to pay for the meals, refreshments, travel, or other expenses for guests of Health Care Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

## **D. SUPPORTING THIRD-PARTY EDUCATIONAL CONFERENCES**

*Bona fide* independent, educational, scientific, and policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective health care. These typically include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers. Companies may support these conferences in various ways:

**1. Conference Grants.** Companies may provide a grant to the conference sponsor to reduce conference costs. They may also provide grants to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are Health Care Professionals in training. Companies may provide grants when: (1) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects the attending Health Care Professionals who are in training. Such grants should be paid only to organizations with a genuine educational function and may be used to reimburse only the legitimate expenses for *bona fide* educational activities. Such grants also should be consistent with applicable standards established by the conference sponsor and anybody accrediting the educational activity. The conference sponsor should independently control and be responsible for the selection of program content, faculty, educational, methods, and materials.

**2. Conference Meals and Refreshments.** Companies may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees. Also, Companies themselves may provide meals and refreshments for Health Care Professional attendees if such meals and refreshments are provided: (1) to all Health Care Professional attendees (with the limited exception noted below), and (2) in a manner that is consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity. Any meals and refreshments should be modest in value, subordinate in time and focus to the purpose of the conference, and clearly separate from the continuing medical education portion of the conference.

**3. Faculty Expenses:** Companies may make grants to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for Health Care Professionals who are *bona fide* conference faculty members.

**4. Advertisements and Demonstration.** Companies may purchase advertisements and lease booth space for Company displays at conferences.

<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

## **E. SALES, PROMOTIONAL, AND OTHER BUSINESS MEETINGS**

Companies may conduct sales, promotional, and other business meetings with Health Care Professionals to discuss, for example, Medical Technology features, sales terms, or contracts. Often, these meetings occur close to the Health Care Professional's place of business. It is appropriate to pay for reasonable travel costs of attendees when necessary (e.g., for plant tours or demonstrations of non-portable equipment) and/or to provide occasional modest meals and refreshments in connection with such meetings. However, it is not appropriate to pay for meals, refreshments, travel, or lodging of guests of Health Care Professionals or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

## **F. CONSULTING ARRANGEMENTS WITH HEALTH CARE PROFESSIONALS**

Companies engage Health Care Professionals to provide a wide-range of valuable, *bona fide* consulting services through various types of arrangements, such as contracts for research, product development, development and/or transfer of intellectual property, marketing, participation on advisory boards, presentations at Company-sponsored training and other services. Companies may pay consultants fair market value compensation for performing these types of services, provided that they are intended to fulfill a legitimate business need and do not constitute an unlawful inducement. Companies should comply with the following standards in connection with consulting arrangements with Health Care Professionals:

- Consulting agreements should be written and describe all services to be provided. When a Company contracts with a consultant to conduct clinical research services, there should also be a written research protocol.
- Consulting arrangements should be entered into only where a legitimate need for the services is identified in advance and documented.
- Selection of a consultant should be made on the basis of the consultant's qualifications and expertise to meet the defined need.
- Compensation paid to a consultant should be consistent with fair market value in an arm's length transaction for the services provided and should not be

<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

based on the volume or value of the consultant’s past, present or anticipated business.

- A Company may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, modest meals, and lodging.
- The venue and circumstances for Company meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information.
- Company-sponsored meals and refreshments provided in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting. Companies should not provide recreation or entertainment in conjunction with these meetings.
- A Company’s sales personnel may provide input about the suitability of a proposed consultant, but sales personnel should not control or unduly influence the decision to engage a particular Health Care Professional as a consultant. Companies should consider implementing appropriate procedures to monitor compliance with this section.

**1. Provisions on Payment of Royalties.** Arrangements involving the payment of royalties to a Health Care Professional should meet the contractual standards set forth above. Health Care Professionals, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or Medical Technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement. A Company should enter into a royalty arrangement with a Health Care Professional only where the Health Care Professional is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method. A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented.

The calculation of royalties payable to a Health Care Professional in exchange for Intellectual Property should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. For example, royalties paid

<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

in exchange for Intellectual Property should not be conditioned on: (1) a requirement that the Health Care Professional purchase, order or recommend any product or medical technology of the Company or any product or technology produced as a result of the development project; or (2) a requirement to market the product or medical technology upon commercialization. (Companies may, however, elect to enter into separate consulting agreements with Health Care Professionals for marketing services.) Companies are strongly encouraged to consider whether it is appropriate and practicable to exclude from the calculation of royalties the number of units purchased, used, or ordered by the Health Care Professional and/or members of the Health Care Professional's practice.

**G. PROHIBITION ON ENTERTAINMENT AND RECREATION**

Company interactions with Health Care Professionals should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, a Company should not provide or pay for any entertainment or recreational event or activity for any non-employee Health Care Professional. Such activities include, for example, theater, sporting events, golf, skiing, hunting, sporting equipment, and leisure or vacation trips. Such entertainment or recreational events, activities, or items should not be provided, regardless of: (1) their value; (2) whether the Company engages the Health Care Professional as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.

**H. MODEST MEALS ASSOCIATED WITH HEALTH CARE PROFESSIONAL BUSINESS INTERACTIONS**

A Company's business interactions with Health Care Professionals may involve the presentation of scientific, educational, or business information and include, but are not limited to, the different types of interactions described in Sections C through G of this Code of Ethics. Such exchanges may be productive and efficient when conducted in conjunction with meals. Accordingly, modest meals may be provided as an occasional business courtesy consistent with the limitations in this section.

- 1. Purpose.** The meal should be incidental to the *bona fide* presentation of scientific, educational, or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event.

<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

2. **Setting and Location.** Meals should be in a setting that is conducive to *bona fide* scientific, educational, or business discussions. Meals may occur at the Health Care Professional’s place of business. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions. In other cases, it may be impractical or inappropriate to provide meals at the Health Care Professional’s place of business, for example, (1) where the Medical Technology cannot easily be transported to the Health Care Professional’s location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained onsite.
3. **Participants.** A Company may provide a meal only to Health Care Professionals who actually attend the meeting. A Company may not provide a meal for an entire office staff where everyone does not attend the meeting. A Company also may not provide a meal where its representative is not present (such as a “dine & dash” program). A Company may not pay for meals for guests of Health Care Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

**I. EDUCATIONAL ITEMS; PROHIBITION ON GIFTS**

A Company occasionally may provide items to Health Care Professionals that benefit patients or serve a genuine educational function for Health Care Professionals. Other than medical textbooks or anatomical models used for educational purposes, any such item should have a fair market value of less than \$100. A Company may not provide items that are capable of use by the Health Care Professional (or his or her family members, office staff or friends) for non-educational or non-patient-related purposes, for example, a DVD player or MP3 player/i-Pod. A Company may not give Health Care Professionals any type of non-educational branded promotional items, even if the item is of minimal value and related to the Health Care Professional’s work or for the benefit of patients. Examples of non-educational branded promotional items include pens, notepads, mugs, and other items that have a Company’s name, logo, or the name or logo of one of its Medical Technologies. Companies also may not provide Health Care Professionals with gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents.

This section is not intended to address the legitimate practice of providing products for evaluation and demonstration purposes.

<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

**J. PROVISION OF COVERAGE, REIMBURSEMENT AND HEALTH ECONOMICS INFORMATION**

As Medical Technologies have become increasingly complex, so have payor coverage and reimbursement policies. Patient access to necessary Medical Technology may be dependent on Health Care Professionals and/or patients having timely and complete coverage, reimbursement, and health economic information. Consequently, a Company may provide such information regarding its Medical Technologies if it is accurate and objective. A Company also may collaborate with Health Care Professionals, patients and organizations representing their interests, to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patients to access its Medical Technologies.

Permissible activities involving the provision of coverage, reimbursement and health economic information may include, but are not limited to:

- Identifying the clinical value of the Company’s Medical Technologies and the services and procedures in which they are used when providing coverage, reimbursement and health economics information and materials to Health Care Professionals, professional organizations, patient organizations, and payors.
- Collaborating with Health Care Professionals, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues; supporting Health Care Professionals and their professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies.
- Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to Health Care Professionals regarding the Company’s Medical Technologies, including identifying coverage, codes and billing options that may apply to those Medical Technologies or the services and procedures in which they are used.
- Providing accurate and objective information about the economically efficient use of the Company’s Medical Technologies, including where and how they can be used within the continuum of care.



<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

- Providing information related to the Company’s Medical Technologies regarding available reimbursement revenues and associated costs.
- Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes in order to facilitate a Health Care Professional’s decision to buy or use the Company’s Medical Technologies.
- Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of the Company’s Medical Technologies.
- Facilitating patient access to the Company’s Medical Technologies by providing Health Care Professionals with assistance in obtaining patient coverage decisions from payors. This assistance may include providing information and/or training on payor policies and procedures for obtaining prior authorization, and providing sample letters and information on medical necessity and appeals of denied claims. In addition, at the request of a Health Care Professional to facilitate patient access to the Company’s Medical Technology, and subject to appropriate privacy safeguards, the Company may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals of denied claims, relating to a Company’s own Medical Technology; however such assistance should not be provided as an unlawful inducement.

A Company may not interfere with a Health Care Professional’s independent clinical decision making or provide coverage, reimbursement and health economics support as an unlawful inducement. For example, a Company should not provide free services that eliminate an overhead or other expense that a Health Care Professional would otherwise of business prudence or necessity have incurred as part of its business operations if doing so would amount to an unlawful inducement. Further, a Company should not suggest mechanisms for billing for services that are not medically necessary, or for engaging in fraudulent practices to achieve inappropriate payment.

**K. RESEARCH AND EDUCATIONAL GRANTS AND CHARITABLE DONATIONS**

A Company may provide research and educational grants and charitable donations. However, a Company may not provide such grants or donations as an unlawful inducement. Therefore, a Company should: (a) adopt objective criteria for providing such grants and

<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

donations that do not take into account the volume or value of purchases made by, or anticipated from, the recipient; (b) implement appropriate procedures to ensure that such grants and donations are not used as an unlawful inducement; and (c) ensure that all such grants and donations are appropriately documented. A Company’s sales personnel may provide input about the suitability of a proposed grant or charitable donation recipient or program, but sales personnel should not control or unduly influence the decision of whether a particular Health Care Professional or institution will receive a grant or donation or the amount of such grant or donation. Companies should consider implementing procedures to monitor compliance with this section.

## 1. Research Grants

Research provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes improved delivery of health care, and otherwise benefits patients. In furtherance of these objectives, a Company may provide research grants to support independent medical research with scientific merit. Such activities should have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of Medical Technologies.

Company-initiated or directed research involving a Company’s Medical Technologies (such as clinical study agreements) is addressed separately in Section F.

## 2. Educational Grants

Educational grants may be provided for legitimate purposes, including, but not limited to, the examples below. A Company may make educational grants to conference sponsors or training institutions. A Company may not make educational grants to individual Health Care Professionals.

- *Advancement of Medical Education.* A Company may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs that are charitable or have an academic affiliation, or other medical personnel. (For additional considerations regarding educational grants, see Section D.)
- *Public Education.* A Company may make grants for the purpose of supporting education of patients or the public about important health care topics.

<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

### 3. Charitable Donations

A Company may make monetary or Medical Technology donations for charitable purposes, such as supporting indigent care, patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should be motivated by *bona fide* charitable purposes and should be made only to *bona fide* charitable organizations or, in rare instances, to individuals engaged in genuine charitable activities for the support of a *bona fide* charitable mission. Companies should exercise diligence to ensure the *bona fide* nature of the charitable organization or charitable mission.

#### L. EVALUATION AND DEMONSTRATION PRODUCTS

Providing products to Health Care Professionals at no charge for evaluation or demonstration purposes can benefit patients in many ways. These benefits include improving patient care facilitating the safe and effective use of products, improving patient awareness, and educating Health Care Professional regarding the use of products. Under certain circumstances described below, a Company may provide reasonable quantities of products to Health Care Professionals at no charge for evaluation and demonstration purposes.

This section is limited to providing evaluation and demonstration products only and is not intended to address any other arrangement

Company products that may be provided to Health Care Professionals for evaluation include single use (e.g., consumable or disposable products) and multiple use products (sometimes referred to as “capital equipment”). These products may be provided at no charge to allow Health Care Professionals to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future. Company products provided for evaluation are typically expected to be used in patient care.

- **Single Use/Consumables/Disposables.** The number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.
- **Multiple Use/Capital.** Multiple use products provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation. The terms

<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

of an evaluation of such multiple use products should be set in advance in writing. Companies should retain title to such multiple use products during the evaluation period and should have a process in place for promptly removing such multiple use products from the Health Care Professional’s location at the conclusion of the evaluation period unless the Health Care Professional purchases or leases the products.

- **Demonstration.** Company demonstration products are typically unsterilized single use products or mock-ups of such products that are used for Health Care Professional and patient awareness, education, and training. For example, a Health Care Professional may use a demonstration product to show a patient the type of device that will be implanted in the patient. Demonstration products typically are not intended to be used in patient care. Demonstration products also are typically identified as not intended for patient use by use of such designations as “Sample,” “Not for Human Use,” or other suitable designation on the product, the product packaging, and/or documentation that accompanies the product.



<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

**FREQUENTLY ASKED QUESTIONS  
REGARDING ADVAMED'S CODE OF ETHICS  
ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS**

**Who are “Health Care Professionals”? Does the term include non-clinical people who make Medical Technology purchasing decisions? Does it include decision-makers within GPOs?**

The phrase “Health Care Professionals” is intended to be a broad one. It includes individuals or entities: 1) which are involved in the provision of health care services and/or items to patients; and 2) which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ Medical Technologies in the United States. The phrase Health Care Professional includes both persons providing services (such as licensed physicians) and persons who do not provide services directly but who are involved in the decision to purchase, lease, or recommend a Medical Technology. These individuals include, for example, purchasing agents, physician’s practice managers and management within group purchasing organizations (“GPOs”).

**Does the Code apply to gifts, meals, refreshments, and other benefits provided by Companies to government employees?**

Yes, the Code applies to gifts, meals, refreshments, and other benefits provided by Companies to government employees if the employees are Health Care Professionals. Companies also should be aware that there may be specific legal restrictions on providing gifts and other benefits to government employees, and that these restrictions may, in some cases, be more restrictive than the Code.

**Does the Code cover interactions with Health Care Professionals whose primary place of work is outside the U.S.? Does it cover interactions outside the U.S. with Health Care Professionals who work in the U.S.?**

The Code applies to interactions with Health Care Professionals to the extent that they provide services or Medical Technologies in the United States. This would include interactions with Health Care Professionals who work in the United States, even if the interaction occurs outside the country (such as at a conference or other event). Of course, there are other laws and ethical requirements that may pertain to interactions with Health Care Professionals located both inside and outside the United States.



<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

**What do the terms “modest” and “occasional” mean?**

“Modest” means moderate value, but may differ depending on regional differences.  
“Occasional” means infrequent.

The provision of meals is subject to the limits discussed in Section H. A Company should consider establishing limits on the frequency and costs of meals provided to Health Care Professionals to comply with the requirement that meals be “modest” and “occasional.”

**May a Company’s employee or agent pay for meals or refreshments for a Health Care Professional that a Company could not provide under the Code, if the Company neither pays for the meals or refreshments nor reimburses the employee or agent?**

No. The Code should be viewed as applying to a Company’s employees and agents even if they pay for benefits themselves. Depending on the circumstances, it may be appropriate for an employee or agent of a Company to engage in certain activities with a Health Care Professional if each pays his or her own way.

**May a Company offer to provide laptop computers with independent value to any purchasing manager whose hospital purchases at least 1,000 units of the Company’s medical technology that the Company has just introduced?**

No. A Company may not provide any item of value to a Health Care Professional that takes into consideration the value or volume of the business that is or may be generated by the Health Care Professional, unless permitted by law (e.g., appropriate discounts).

**May a Company provide support for a Health Care Professional-sponsored social event, such as an office holiday party?**

No, such support would be inappropriate.

**Why may it be appropriate under the Code for Companies to pay for travel to attend training and education sessions?**

In order to efficiently deliver training and/or education at appropriate facilities, the Code contemplates that a Company may bring Health Care Professionals together at a central location, which may make out-of-town travel necessary. Note that this section deals only



<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

with meetings focused on training and education on Medical Technologies, and only for persons who could legitimately benefit from the training and education. (Meetings focused on sales, promotional, and other business meetings are discussed in Section E.)

**May a Company pay for travel to a Company-sponsored general educational program (not related to a Medical Technology)?**

It may be appropriate for a Company to conduct a general educational session, but it is not the type of program for which Company-supported travel would be appropriate under the Code. In contrast, paying for a Health Care Professional’s travel may be appropriate when the Company is conducting training and education on the safe and effective use of its Medical Technologies.

**May a Company designate attendees or faculty who will speak at a third-party educational conference?**

No. The Code contemplates that an independent third party will select faculty and attendees. The Code does not preclude a Company from recommending a knowledgeable faculty member, where the recommendation is permitted by the conference sponsor’s guidelines. The ultimate selection should be made by the conference sponsor.

**May a Company provide an educational grant to support the attendance of a Health Care Professional at a third-party educational conference?**

The Code contemplates that grants would be made to the conference sponsor or training institution, which will select the attendees. Furthermore, the Code contemplates that the benefited attendees would be medical students, residents, fellows, or other Health Care Professionals in training.

**If a Company provides a grant for a medical student to attend an educational conference, may the funds be used to cover both travel expenses and registration fees?**

Yes, provided that the grant is given directly to a training institution or a third party educational conference sponsor.

**May a Company sponsor an off-site sales, promotional, or other business meeting that is ancillary to a third-party educational conference?**

<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

Yes, provided that the sales and promotional meeting or other activity has a legitimate business purpose and meets all applicable requirements of the Code. The Company also should comply with applicable conference sponsor guidelines.

**Why does the Code not allow Companies to extend business courtesies to guests/spouses in connection with sales, promotional and other business meetings?**

AdvaMed’s Code of Ethics is mindful of the desire to avoid even the appearance that business courtesies are being given as improper inducements to promote a Company’s Medical Technologies. On the other hand, Companies may, as a matter of common courtesy and civility, provide occasional modest meals or refreshments for Health Care Professionals in connection with these types of meetings that are conducive to the exchange of information. The Code precludes the extension of these courtesies to persons, such as guests/spouses, without a *bona fide* professional interest in the meeting.

**May a Company conduct a sales, promotional, or other business meeting at a resort location and pay for a Health Care Professional’s travel to the meeting?**

Generally, this would not be appropriate. Companies should be deliberate in selecting the location and venue for such meetings. Like location and venue selection for training and education meetings, Companies should select a location and venue that is appropriate for, and conducive to, accomplishing the purpose of the meeting. Selection of a resort location would not likely meet these standards and may give rise to an appearance of impropriety. In addition, the location should be evaluated for consistency with the provisions in Section E, which state that it may be appropriate at sales, promotional, or other business meetings to provide occasional modest meals or refreshments and, with respect to providing travel, that the travel be “necessary.” Furthermore, the Code provides for limited special circumstances of “plant tours and demonstrations of non-portable equipment” as specific examples of when travel might be necessary.

**May a Company indirectly provide meals or refreshments when the provision of meals or refreshments does not conform to the Code, for example, by reimbursing a distributor who provides these meals while marketing the Company’s Medical Technologies?**

No. Companies should always promote adherence to the Code by intermediaries when they are engaged in marketing the Company’s Medical Technologies. A Company should never knowingly encourage or condone an intermediary’s engaging in conduct that would be prohibited by the Code if a Company engaged in it directly.

<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

### **How are Clinical Study Agreements treated under the Code?**

Arrangements that involve the provision of clinical research services by a Health Care Professional in return for compensation are a type of consulting arrangement and are subject to the same principles as other consulting arrangements under the Code. They should be governed by a written services agreement, and compensation should be based on fair market value for the services provided. The clinical program for which the services are being provided should fulfill a legitimate research purpose.

A Clinical Study Agreement typically is entered into between a Company and a Health Care Professional that is a facility, institution, or practice group, and compensation for the clinical research services is paid to that entity. An individual Health Care Professional may act as a study investigator but also provide related services in his or her individual capacity that is outside the scope of the services covered in the clinical study agreement (e.g., protocol development). In that case, it may be appropriate to enter into a separate consulting arrangement with that Health Care Professional.

### **How can a Company establish “fair market value”?**

There are different valuation methods that may be used to establish fair market value. In all instances, a Company should use objective, verifiable criteria. The method or methods used by a Company should be documented.

### **What is considered a “legitimate need” to engage a Health Care Professional as a consultant?**

A legitimate need arises when a Company requires the services of a Health Care Professional in order to achieve a proper business objective. There are many proper business objectives. However, engaging a Health Care Professional for the purpose of generating business directly from such Health Care Professional (or a health care provider that is affiliated with the Health Care Professional) is not a proper business objective. Thus, there is a legitimate need to engage a Health Care Professional only if the arrangement would have been entered into absent an opportunity to generate business directly from the Health Care Professional. Further, the level of consulting services to be obtained from a Health Care Professional should not exceed the amount that is reasonably necessary to achieve a Company’s proper business objective.

<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

**May a Company’s employee or agent pay for entertainment or recreation for a Health Care Professional that a Company could not provide under the Code, if the Company neither pays for the entertainment or recreation nor reimburses the employee or agent?**

No. The Code should be viewed as applying to a Company’s employees and agents even if they pay. Depending on the circumstances, it may be appropriate for an employee or agent of a Company to engage in certain activities with a Health Care Professional if each pays his or her own way.

**Is a general discussion to build good business relationships a “business presentation” such that it is appropriate to provide a business meal?**

No. A business presentation may include substantial discussions related to medical technology development and improvement of a medical technology, pricing, or contract negotiations. The business discussion should account for most of the time spent during the meal. Development of general goodwill and business relationships should not be the primary purpose of a business meal, and a business meal should not be used for entertainment or recreational purposes.

**May a Company provide a gift such as flowers, gift baskets, meals, snacks, wine, or other refreshments to a Health Care Professional or a Health Care Professional’s office or staff?**

No. These types of gifts and refreshments are not considered educational items or for the benefit of patients.

**May a Company give gifts to staff of a Health Care Professional who are not themselves Health Care Professionals?**

Gifts given to the staff of a Health Care Professional should be treated as though they are given to the Health Care Professional and are subject to all applicable provisions of the Code.

**May a Company or its representative provide a gift to recognize a life event for a Health Care Professional, such as a wedding, birth, anniversary, or death of a family member?**

No. A Company, or representative acting on the Company's behalf, may only provide items to Health Care Professionals that are intended for the benefit of patients or serve a genuine



<b>TITLE:</b>	<b>Code of Ethics on Interactions with Healthcare Professionals</b>	<b>POLICY: LGL 8050.03 WW</b>
<b>Effective Date:</b>	February 1, 2018	<b>Revision: D</b>
<b>Policy Address</b>	Accuray University	

educational function for the Health Care Professional. Gifts such as flowers, fruit baskets, etc. do not meet this requirement even if provided to recognize a significant life event.

**May a Company raffle an item during a trade show, such as two round-trip airline tickets, that it could not otherwise give as a gift?**

No. A Company may not raffle or give away at a trade show an item that it could not otherwise give a Health Care Professional under Section I.

**What types of items are considered to be for the benefit of patients?**

Items intended for the benefit of patients could include starter kits, and educational brochures, for example. However, “scrubs” and office supplies would not be considered an item for the benefit of patients.

**May a Company pay for or provide tickets to a Health Care Professional or spouse or guest to attend charitable events, such as galas and golf outings?**

No. A Company may not pay for or provide tickets to Health Care Professionals or their spouses or guests to attend charitable events, such as galas and golf outings.

**May a Company give a Health Care Professional a research grant that is unrestricted and can be used for any purpose?**

No. A Company should give research grants only if they are in support of research that has defined goals, objectives, and milestones.

**May a Company make a contribution in support of a Health Care Professional’s charitable event (e.g., golf tournament, outing, gala dinner, and the like), where the proceeds earned from the event will be used for charitable purposes?**

Yes, so long as the donation is not an unlawful inducement. However, a Company may not pay for an individual Health Care Professional to attend or participate in the charitable event.