# BioXcel Therapeutics, Inc.

# HEALTHCARE COMPLIANCE MANUAL

Dear BioXcel Team:

As you know, the mission of BioXcel is to help support patients who are in need of innovative medicine that meet unmet medical needs. Consistent with this focus on patients, BioXcel Therapeutics is committed to maintaining a positive, ethical, and compliant culture. This culture and commitment to doing the right thing for our patients, healthcare providers and our employees, is key to the way we conduct business. To help ensure that the Company's activities are carried out in an ethical and compliant manner, we have implemented the fundamental building blocks of a comprehensive healthcare compliance program, which include:

- Designation of a Compliance Officer and formation of a Compliance Committee,
- Written policies, procedures, and standards of conduct,
- Effective compliance training and education,
- Establishing effective lines of communication, including implementation of an anonymous hot line number for employees to use to ask questions or report alleged misconduct,
- Internal monitoring and auditing activities,
- Consistent enforcement of standards of conduct, and
- Undertaking corrective actions for detected offenses.

This Healthcare Compliance Manual is an introduction to the BioXcel Therapeutics Compliance Program. It describes how we operate and includes the foundational concepts that direct each employee's business activities in support of the Company. The Compliance Program also includes specific policies, procedures, training, monitoring, and auditing activities designed to ensure that it is effective and that our employees have the tools they need to work in a compliant and ethical manner.

The Company encourages open and honest communication. If you see, hear, or learn about any improper or unethical activities, or if you are asked to conduct yourself in a manner that makes you uncomfortable or that you think may be a violation of the law or Company policies, we ask that you please promptly report this information. Each of us is responsible for understanding this Healthcare Compliance Manual and all associated policies and procedures. In doing so, we will demonstrate our commitment to the patients we serve.

I strongly encourage all of you to take full advantage of the Compliance Program and associated resources that we have made and will continue to make available, and that you take the time to read and understand our policies and expectations for compliant and ethical behavior as a member of the BioXcel Therapeutics' team. Thank you again for your commitment and dedication to BioXcel Therapeutics.

Thank you,

Vimal Mehta
CEO and Co-Founder

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# 1. INTRODUCTION

## 1.1 Commitment to Compliance

At BioXcel Therapeutics, Inc. ("BioXcel" or the "Company"), we utilize artificial intelligence, or AI, approaches to develop transformative medicines in neuroscience and immuno-oncology. We are focused on utilizing cutting-edge technology and innovative research to develop high-value therapeutics aimed at transforming patients' lives. Consistent with our mission and focus on patients, we are also committed to maintaining a positive, ethical and compliant culture. This culture, and BioXcel's commitment to doing the right thing, will drive the way we do business.

To support our commitment to compliance and ethics, BioXcel has developed this Healthcare Compliance Manual ("Manual"), a Code of Business Conduct and Ethics, and policies and procedures that are designed to ensure compliance with applicable laws, rules, regulations, industry codes and ethical standards.

In furtherance of its commitment to compliance and ethics, BioXcel has appointed a Compliance Officer and established a comprehensive compliance program (the "Compliance Program") which includes policies and procedures and training activities to ensure compliance with laws and regulations applicable to our business. All BioXcel employees, directors, officers, agents, representatives, independent contractors, and other third parties acting on BioXcel's behalf ("BioXcel Personnel") are expected to comply with this Manual and understand its application to BioXcel's business and to their specific job function.



Although the laws and regulations applicable to our business are complicated, at their core they can be boiled down to three key principles:

- BioXcel must promote its products and services in compliance with approved labeling and applicable laws, rules and regulations;
- BioXcel can never offer bribes, rewards, gifts, hospitality or other items of value to induce healthcare providers ("HCPs") to recommend, purchase, supply or administer BioXcel products, or to reward HCPs' favorable treatment of BioXcel products; and
- BioXcel can never exert improper influence on medical decision-making or interfere with patient care.

## 1.2 Scope and Purpose

This Manual serves as a resource for many of the activities in which all BioXcel Personnel engage in on behalf of BioXcel. BioXcel Personnel should read this Manual in conjunction with the Code of Business Conduct and Ethics and applicable BioXcel policies and procedures. If you have any questions or concerns about these documents, you should contact your immediate supervisor, the Compliance Officer or Legal Department.

### 1.3 Duty to Report

This Manual does not answer all compliance questions or address all situations that may arise in day-to-day operations. Accordingly, the Company, therefore, expects and encourages an open and honest environment where questions and potential problems or concerns can, and should, be raised. If you see, hear or know about any improper, unethical, or illegal activities, or if you are asked to conduct yourself in a manner that makes you uncomfortable or that you think may be a violation of the law or Company policies, you have a duty to promptly report the information. You can report potential problems or concerns directly to your manager, a Human Resources representative, the Compliance Officer or Legal Department, or through one of the methods listed below, which are available 24 hours a day, 7 days a week:

- Toll-Free Hotline: (844) 718-1224
- Website: www.bioxceltherapeutics.ethicspoint.com
- Mobile Device: bioxceltherapeutics.navexone.com

BioXcel has a strict non-retaliation policy, which prohibits retaliation, harassment or any other improper adverse action against BioXcel Personnel who make a good faith report of any known or suspected violation or seeks assistance in addressing a compliance concern. Any BioXcel Personnel that is found to have retaliated in violation of the Company's non-retaliation policy will be subject to discipline, up to and including termination.

## 2. OVERVIEW OF APPLICABLE LAWS AND GUIDANCE

There are a number of laws, regulations, guidance and industry codes that impact our business. BioXcel Personnel are expected to have a general understanding of these laws, regulations, guidance and industry codes and how they impact their job responsibilities.

| LAW | DESCRIPTION OF LAW |
|---|---|
| **Anti-Kickback Statute** | Prohibits the exchange of anything of value with the intent to directly or indirectly influence or reward the referral or recommendation of business or services that are payable by a federal program, such as Medicare/Medicaid or the VA. Applies to HCPs, office staff and anyone in a position to influence the referral or recommendation of business. |
| **Food, Drug & Cosmetic Act and Regulations** | Governs oversight of pharmaceutical products including, product quality, product safety and product promotional activities. |
| **False Claims Act** | Prohibits entities and individuals from knowingly submitting or causing someone else to submit a fraudulent or false claim for reimbursement to a government-funded healthcare program, such as Medicare/Medicaid or the VA. |

| | |
|---|---|
| **Anti-Bribery Laws** | Forbids making, offering or promising any payment or anything of value (directly or indirectly) to a government official, including foreign political parties and candidates and employees of government-funded healthcare institutions, including HCPs, with an intent to influence an official act or decision to obtain or retain business or secure an unfair business advantage. |
| **Privacy & Data Protection Laws (HIPAA)** | Requires the responsible management of individuals' personally identifiable information – information that can be used to identify, locate or contact an individual ("Protected Health Information"). |
| **Antitrust Laws** | Prohibits agreements that may unreasonably restrict competition, such as price-fixing conspiracies, and predatory efforts to eliminate competition or restrict trade. |
| **Sunshine Act & State Disclosure Laws** | Mandates that manufacturers of products covered by federal healthcare programs disclose payments and transfers of value provided to HCPs and teaching hospitals. |
| **State Spending Limit Laws** | Imposes spending limits on certain activities that are otherwise permitted, such as meals with HCPs. Applies to HCPs licensed in that state regardless of whether the HCP is also licensed in or practices in another state, and regardless of where the meal takes place. |
| **State Lobbying Laws** | Requires certain representatives of pharmaceutical and medical device companies who interact with government officials (such as members of a state formulary committee) or HCPs who practice at a state-funded hospital or clinic, to register as lobbyists. |
| **Prescription Drug Marketing Act** | Prohibits the sale, purchase, or trade of a prescription drug sample, whether by the manufacturer or by the HCP who receives the sample from the manufacturer. Makes it illegal for HCPs to attempt to obtain reimbursement for a drug sample. |
| **PhRMA Code** | Addresses interactions between the medical community and pharmaceutical companies, including consulting arrangements, speaker programs, gifts, entertainment, meals, educational items grants for independent medical education and research interactions. |
| **OIG Compliance Program Guidance** | Promotes the development of internal policies that adhere to laws, regulations and guidelines applicable to pharmaceutical manufacturers. |

# 3. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

A healthcare professional ("HCP") is defined as any person or entity in the position to purchase or prescribe or to arrange for or recommend the purchase or prescription or formulary placement of any BioXcel product. This includes, but is not necessarily limited to, physicians, nurses, physician's assistants, nurse practitioners, hospitals, pharmacists, and medical directors, as well as any individual employed by such persons or entities. The definition of HCP does not include individuals who are themselves BioXcel employees.

## 3.1 Communications

### 3.1.1 General

All communications by BioXcel Personnel whether verbal, written, or electronic (including texts, emails, reports, business planning documents, voicemails, handwritten notes) should be conducted in accordance with BioXcel policies, procedures, and trainings, including any specific guidelines for communicating with patients and HCPs. When communicating with others, it is always advisable to comply with the following guidance:

- Always state facts and avoid assumptions;
- Be cautious about your tone and avoid the use of colorful or overly descriptive language;
- Write clearly and simply and include context so that you can be understood by your intended audience, and by those who may read your words later;
- Keep in mind that it may be better to pick up the phone rather than committing something to writing to avoid misinterpretation later;
- Ensure that the communication is being sent to the intended recipient and, if responding to an email, consider whether or not it is appropriate to hit "reply all" and also review the entire email chain so that you understand the entire context of the email;
- Never disclose personal information;
- If inappropriate or questionable emails are received, consult with the Compliance Officer or the Legal Department before responding.

### 3.1.2 Promotional Communications

All Company interactions with HCPs should be professional in nature and facilitate the exchange of medical, scientific, or educational information, with the goal of ultimately benefiting patient care. Promotional communications, which are communications intended for the purpose of promoting, marketing or selling BioXcel products, must also be consistent with FDA-approved product labeling, such as the prescribing Information, and HCP interactions must always be truthful, balanced and non-misleading, in a manner that presents both the benefit and risk profile of Company products.

### 3.1.3 Approved Promotional Materials Only

Promotional communications include materials and communications that make affirmative or implied claims about the safety or efficacy of the product or that otherwise encourage the use, purchase, sale or recommendation of a product. All promotional communications, whether written or oral, including advertising, promotional labeling, other promotional materials and, in certain circumstances, corporate communications and press releases ("Promotional Materials") must be reviewed and approved by BioXcel's Medical, Legal and Regulatory Review Committee ("MLR") or other Company designated review process.

All Promotional Materials must:

- Be truthful, accurate and non-misleading and consistent with the product labeling and applicable laws, regulations and BioXcel policies;
- Have fair balance between the stated product benefits versus the product risks, warnings, precautions, limitations and other material safety information;
- Be supported by substantial evidence;
- Not make comparative or superiority claims vs. competitor products without appropriate and substantial evidence; and
- Not minimize risk.

Approvals of Promotional Materials are specific to an intended use and audience and, therefore, are not universal. Any modification to approved Promotional Materials, including use by a different team or for a different event, will require re-review and approval of the Promotional Material for that specific use and audience.

Approved Promotional Materials may not be marked, highlighted or otherwise altered in any way.. All reprints must be approved by MLR and may only be used as approved and instructed by MLR.

The decision of an HCP to prescribe or recommend a BioXcel product or service must be based on the HCP's medical judgment and not on any item of value offered by BioXcel Personnel to the HCP. When interacting with HCPs, no BioXcel Personnel shall promise to provide or provide anything of value to the HCP as a reward or inducement for the HCP's business (also known as "quid pro quo").

### 3.1.4 Email and Text Communications

Emails from employees to any external party should not include any product efficacy or safety information as this may trigger certain federal regulatory requirements. Employees who would like to email such information should submit the material to MLR for review and approval prior to use.

Generally, routine day-to-day business correspondence (*e.g.*, discussing logistics for a meeting) that is within the scope of BioXcel Personnel's role does not need to be approved. However,

BioXcel Personnel should not use text messages or messaging apps (e.g., WhatsApp) with customers for business purposes.

### 3.1.5 Pre-Approval Communications

FDA prohibits manufacturers from representing in a promotional context that an investigational new drug or device is safe or effective for the purposes and uses for which it is under investigation. This is viewed by FDA as "Pre-Approval" promotion and is an area of continuing oversight by FDA.

Prior to FDA approval, there are certain circumstances referred to as *bona-fide* exchanges of scientific information ("Scientific Exchange") where Medical BioXcel Personnel may engage in limited clinical discussion of an investigational drug with HCPs, academicians, and external scientists. When doing so, the communications:

- Must indicate that the product is investigational;
- Must NOT say or imply that the product is approved, efficacious, safe or superior to another treatment;
- Must be truthful, non-misleading, balanced, unbiased, and accurately present clinical data with the aim of advancing scientific knowledge and discussion;
- Must be scientific in tone;
- Must be clearly separated from commercial activities and must not be promotional in tone or content; and
- Must be reviewed and approved in advance by MLR.

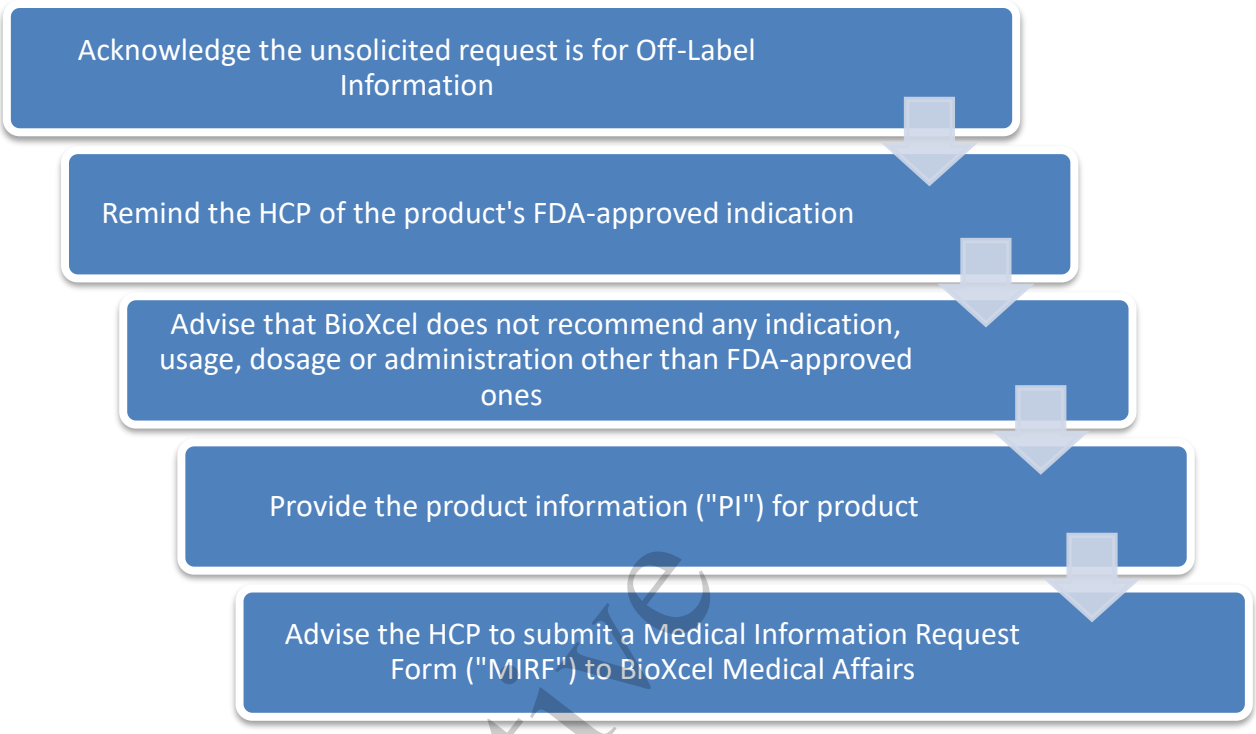
When engaging in Scientific Exchange, Medical BioXcel Personnel should be mindful not to draw conclusions regarding study results (*i.e.*, use data to convey results; use terms such as "safe", "efficacious" or "groundbreaking").



### 3.1.6 Off-Label Promotion and Unsolicited Requests

BioXcel Commercial Personnel (*e.g.*, Field Sales, Marketing, Market Access, Commercial Operations, etc.) must never discuss information about an unapproved product or unapproved use of an approved product ("Off-Label Information") with an HCP even in response to an independent question or inquiry from an HCP that was not prompted, suggested or somehow influenced by the BioXcel Personnel ("Unsolicited Request"). If an HCP initiates a discussion that is inconsistent with the scope of the package insert, BioXcel Commercial Personnel must NOT provide any Off-Label Information, refer the HCP to the package insert, and inform the HCP that BioXcel does not recommend any indication, usage, dosage, or administration other than those that are consistent with the package insert.

If BioXcel Commercial Personnel receives an Unsolicited Request, they should follow the process described below.






BioXcel Medical Affairs Personnel will respond to an Unsolicited Request for Off-Label Information in accordance with its SOPs. BioXcel Commercial Personnel may contact BioXcel Medical Affairs Personnel to follow-up on the status of an HCP's Unsolicited Request for Off-Label Information, but may not discuss the request with the HCP other than to confirm that the HCP's request was fulfilled. BioXcel Commercial Personnel may not request or receive the content or subject matter of a MIRF, and no BioXcel Personnel may proactively distribute MIRFs to HCPs.

### 3.1.7 Non-Promotional Communications

BioXcel Medical Affairs Personnel may receive medical inquiries from HCPs, including Unsolicited Request for Off-Label Information ("Medical Inquiries") and respond to Medical Inquiries in a response that is truthful, accurate, non-misleading, fairly balanced, non-promotional, and scientific in nature, in accordance with its established SOPs. All Medical Inquiries and the BioXcel Medical Affairs Personnel's response to such inquiries must be documented appropriately in accordance with SOPs. BioXcel Medical Affairs Personnel may engage in proactive scientific interactions with HCPs related to:

- Disease state awareness relevant to BioXcel's business;
- Label changes, safety changes or other complex scientific and medical information regarding the safe and appropriate use of BioXcel products;
- Discussion and provision of BioXcel-approved clinical trial data to investigators or consultants;
- Obtaining information and soliciting feedback related to BioXcel-sponsored clinical trials; and

- MLR-approved on-label product presentations.

All Non-Promotional communications (including emails) and materials must:

- Be non-promotional in appearance and intent;
- Not include promotional claims;
- Be appropriately tailored to the intended audience;
- Be truthful, accurate, and not misleading;
- Be clear, balanced and complete;
- Be supported and substantiated by using appropriate, rigorous and adequate scientific and clinical evidence;
- Present information objectively;
- Avoid opinions and conclusions;
- Not include any patient specific information, and
- Not include any elements of branding associated with a product.

BioXcel is also committed to compliance with PhRMA's Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results; the International Committee of Medical Journal Editors ("ICMJE") Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals; the Committee of Publication Ethics ("COPE"); and the International Society for Medical Publication Professionals ("ISMPP") Good Publication Practice for Communicating Company-Sponsored Medical Research ("GPP3"). For more information on publications, see the "Publications" section of this Manual.



### 3.1.8 Health Economics and Outcomes Research

Health Economics and Outcomes Research ("HEOR") provides an analysis of the economic aspects of health and healthcare, including the costs and consequences of healthcare interventions and the effect of healthcare interventions on patient-related clinical, humanistic, and economic outcomes. HEOR information may come from real-world evidence, clinical outcomes assessments, patient-reported outcomes, and clinical studies and can help identify unmet needs, address evidence gaps, supplement controlled trials with real world data, and illustrate a product's value. HCPs and patients use HEOR information to assist their decisions to prescribe or use a specific drug or device. HEOR information and any materials being used for external communications (*e.g.*, posters, abstracts, publications) that include any data/information received from third party sources (*e.g.*, HCPs, research institutions) must be reviewed and approved by MLR prior to use. All HEOR information must be compliant with federal and state privacy laws and any patient information used must be de-identified.

### 3.1.9. Payor Communications

Senior BioXcel management (generally, senior director level and above) may meet with senior management of potential or actual customers, such as payors and physician groups, as well as

non-customers, such as investors, government officials, vendors and other third parties, regarding:

- Corporate capabilities, including potential collaborations;
- A high-level overview of BioXcel products;
- An exchange of strategic imperatives and/or business objectives; or
- Negotiation of pricing or contracting terms.

While generally these interactions are not "promotion" of BioXcel products, FDA has occasionally looked to statements made in such interactions as evidence of intent to promote products and thus, subject to FDA regulation. Accordingly, BioXcel senior management should be cautious in such senior-level interactions, and avoid statements regarding BioXcel products and associated activities that reflect an intention that is not consistent with the Company's legal obligations, policies, or procedures, or that could be harmful to the Company's reputation.

The following guidelines apply to these senior-level interactions:

- BioXcel senior management may only use MLR approved materials and messaging;
- All statements about BioXcel approved products must be consistent with the approved label, fairly balanced, truthful, and non-misleading;
- Any statements about investigational products or pipeline candidates and future potential indications of marketed products must be truthful, not downplay risks relative to benefits, be non-promotional in nature, and make clear that FDA has not approved the investigational product;
- Conclusions about the safety or effectiveness of the investigational product, or about other aspects of the anticipated indication or potential labeling should be avoided;
- Statements made should be consistent with those reviewed by MLR;
- Statements about potential commercialization, such as anticipated pricing, expected sales, or healthcare economic impact, should generally be limited to investor communications;
- Statements about product pricing, including anticipated rebates, discounts or other arrangements, must be consistent with approved government pricing strategy; and
- Statements about relationships with prescribers and payors may not be interpreted as suggesting that BioXcel is inducing physician prescribing, formulary placement or other clinical decisions via an economic relationship or financial incentive.

### 3.1.10 Social Media

BioXcel may use Company-sponsored social media to provide updates and information about BioXcel or its products, including, but not limited to, the use of Facebook, Twitter, Instagram,

YouTube or LinkedIn ("BioXcel-Sponsored Social Media"). Only authorized BioXcel Personnel can speak or post on behalf of the Company regarding any BioXcel product, in accordance with review and approval by the MLR. All BioXcel-Sponsored Social Media must clearly disclose that it is sponsored by BioXcel and any promotional communications that contain claims about the efficacy or safety of a BioXcel product must adhere to appropriate promotional review standards (*e.g.*, truthful and not misleading, consistent with the package insert, etc.).

BioXcel Personnel may not use personal social media (*e.g.*, Twitter, Facebook, LinkedIn, Instagram or blogging) for the purposes of promoting or discussing any BioXcel product or any confidential or sensitive Company information. However, BioXcel employees may:

- "Follow" BioXcel on social media channels; and
- Like, retweet, repost and share any content BioXcel posts on social media accounts, provided that the content is not altered, modified or nullified.

## 3.2 Meals, Gifts and Entertainment

### 3.2.1 General Standards

The transfer of anything of value, including meals, gifts, gratuities, courtesies, favors or entertainment, may not be provided to an HCP in order to, directly or indirectly, influence or encourage the prescription, purchase, lease, recommendation, or sale of any BioXcel product or as a reward for any past or future behavior.

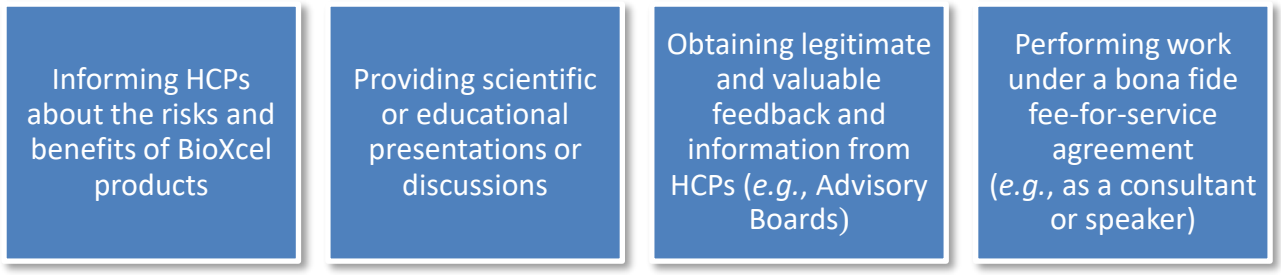
### 3.2.2 Gifts and Entertainment Prohibited

Under no circumstances may BioXcel Personnel offer or provide any gifts, entertainment or recreational activities to HCPs. This includes activities such as taking HCPs to sporting events, giving HCPs tickets to the theater or other events, and holding meetings during a round of golf.

- ✘ **NO** Theater Tickets
- ✘ **NO** Sporting Events
- ✘ **NO** Vacations/Trips
- ✘ **NO** Rounds of Golf

### 3.2.3 Meals

Meals may be provided as a business courtesy to HCPs as part of a *bona fide* scientific, educational or business discussion. Meals with HCPs must only be provided to facilitate a legitimate business purpose and must be incidental to that purpose. Legitimate business purposes may include:




BioXcel Personnel must be present during all meals provided to HCPs or their staff, and an appropriate ratio of HCPs to BioXcel Personnel is required to help ensure that the meal is conducive to business discussion.

### 3.2.4 Requirements for Meals with HCPs

BioXcel Personnel must following the below requirements when providing meals to HCPs:

| MEALS WITH HCPs | |
|---|---|
| **REQUIRED** | **PROHIBITED** |
| ✓ Must be modest by local standards<br>✓ Must only be provided on an occasional basis<br>✓ Must take place in a venue and manner conducive to discussing business matters and/or engaging in a scientific or educational exchange | ✘ Must not include any entertainment<br>✘ Must not be provided to spouses or guests of HCPs who are not themselves HCPs with their own legitimate interest in the information provided |



In accordance with the PhRMA Code on Interactions with Healthcare Providers out-of-office meals by BioXcel Field Sales personnel and their immediate managers are prohibited, except as otherwise expressly permitted under BioXcel policies or with written approval from the Compliance Officer.

### 3.2.5 Spend Limit for Meals with HCPs

Meals with HCPs must adhere to the dollar limits described in the chart below. All spend limits listed refer to meal cost per person, per meal including food AND beverage, taxes, gratuity, and

any service charges. Meal limits may not be combined.

| MEAL/BREAK | LIMIT |
|---|---|
| Breakfast | $ 25 |
| Lunch | $ 40 |
| Dinner | $ 125 |
| In-Office Meals (i.e., In-Service Meals) – breakfast/lunch/dinner | $ 30 |
| Breaks/All-Day Beverage Stations | $ 25 |

State laws may impose different requirements, including those below.

| STATE | RULE | EXCEPTION |
|---|---|---|
| Minnesota | • $50 per year limit | Limit does not apply to meals for HCP consultants and faculty. |
| New Jersey | • $15 limit for breakfast and lunch<br>• $30 limit for dinner | Limit does not apply to educational events and is exclusive of delivery, service fees, taxes or facility rental fees. |
| Vermont | • Meals not permitted for HCPs | Prohibition does not apply to HCP consultants or light refreshments at a conference/seminar booth. |

Costs of meals must alway be modest relative to local standards, but in any case should not exceed applicable spend limits. Special dietary meals (*e.g.*, kosher meals) are attributed to the requesting attendee for reporting purposes if the meal cost is above the applicable meal spend limit.



### 3.2.6 Venue

When the presentation or discussion involves a prescription drug product, BioXcel Field Sales personnel and their immediate managers may provide business courtesy meals in office or in hospital settings only , except as otherwise expressly permitted under BioXcel policies or with written approval from the Compliance Officer.

BioXcel Field Sales personnel and their immediate managers may not attend out of office meals with HCPs hosted by other BioXcel Personnel. Any exceptions must be approved by the Compliance Officer prior to the meal.

All other BioXcel Personnel, at the discretion of management, may provide business courtesy meals to HCPs in a venue and manner conducive to discussing business matters and/or engaging in a scientific or educational exchange of information. Meals should never be provided to spouses or guests of HCPs, who are not themselves HCPs with their own legitimate interest in the information provided.

### 3.2.7 Documentation of Meals

All BioXcel Personnel who coordinate and facilitate meetings involving meals must ensure that there is a written record of the meal served to and consumed by the HCP by using a "Sign-in" sheet. Every individual in attendance where a meal is provided should complete each section of the Sign-in Sheet in full. A signature is required for all attendees. Anyone who does not participate in the meal should still sign-in and check the "Opt-out" box below their signature so the meal will not be attributed to any HCP for reporting purposes. Sign-in sheets should also inform Minnesota, New Jersey and Vermont HCPs that they may not participate in certain meals due to state meal limits in their states.

### 3.2.8 Meals with HCP Consultants

BioXcel Personnel may provide modest meals or receptions to HCP consultants during BioXcel-sponsored meetings or in connection with the provision of services under a valid consulting agreement (*e.g.*, meals provided in connection with speaker training meetings or advisory boards). Meals must follow the guidelines as outlined above.

### 3.2.9 Light Refreshments

Light refreshments (*e.g.*, coffee, tea, water, candy) may be provided at scientific congresses, meetings and exhibit booths and are not considered meals.

## 3.3 Educational and Patient-Related Items

BioXcel Personnel may occasionally provide an educational or patient-related item to better educate an HCP if the item is:

- Not Promotional;
- Not of Substantial Value ($100 or less);
- Not Valuable to the HCP Outside of their Professional Responsibilities; and
- Approved in advance by Compliance.

Homemade items, or items purchased with personal funds, should never be distributed, provided or offered to HCPs. All educational items and patient-related items provided to HCPs must be tracked and documented properly so BioXcel can comply with transparency law reporting requirements.

# 4. ENGAGEMENT OF HCPs

BioXcel may obtain consulting or speaking services from individuals, including HCPs and other professionals, to assist BioXcel in achieving its legitimate business objectives. HCPs may only be engaged as consultants or speakers based on their qualifications and only for legitimate business purposes. All engagements with HCPs must be reflected in a written agreement that must be reviewed and approved by the Legal Department.

BioXcel does not enter into business relationships with any "ineligible individual or entity" and has implemented processes to ensure that any individual or entity with whom it intends to engage for services, has not been excluded, debarred, suspended or otherwise is ineligible to participate in federal healthcare programs or federal procurement programs nor is or has been the subject of an investigation or criminal conviction. All physicians credentialed by BioXcel are required to disclose any criminal conviction or exclusion action or criminal offense related to the provision of healthcare items or services. Initially, and thereafter at least on a regular basis, all credentialed physicians, independent contractors, and vendors are subject to due diligence checks.

Product and compliance training is required for all consultant or speakers. Training should take place in a setting that is conducive to the effective transmission of information, such as:

- Clinical, educational or conference settings;
- Hotels or other commercially available meeting facilities; or
- The HCP's professional location.

### 4.1 HCP Nomination and Selection

BioXcel Personnel (except for Field Sales) may nominate potential consultant candidates based their qualifications and expertise directly related to a legitimate business need. When nominating an individual as a candidate, BioXcel Personnel must not consider the candidate's current or potential prescribing practices nor any potential business gain or loss. All nominations should be submitted to BioXcel Medical Affairs Personnel, and include the HCP's CV and other documentation sufficient to evaluate key opinion leader ("KOL") tiering.

To be selected as a consultant the HCP must: (i) be licensed (and in good standing) in a state to practice his or her respective professional service, and (ii) have experience in the relevant therapeutic area.



### 4.2 Promotional Speaker Programs

BioXcel may engage sufficiently qualified HCPs to educate and promote BioXcel products on its behalf. All such speaker presentations must be consistent with the product's label and off-label promotion is prohibited. BioXcel shall control the content for all speaker programs. An HCP speaker may only use content approved in advance by MLR prior to its use. In determining where a speaker program will be held and whether or not a meal will be provided, BioXcel Personnel responsible for the speaker program must ensure that the venue: (1) is conducive to the exchange of product/educational information; (2) is considered modest by local standards; and (3) does not involve recreation or any entertainment component.

### 4.3 Advisory Boards

BioXcel may engage HCP consultants for advisory board meetings. The purpose of an advisory board meeting is to obtain meaningful and necessary medical, scientific or commercial feedback

and information that is not otherwise available to BioXcel. This may include information regarding disease states, the marketplace, treatment practices, therapeutic inventions, safety, customers, patients and their needs. The purpose of the meeting cannot be to change, influence or reward the prescribing behaviors of the invited HCPs. The agenda for an advisory board meeting should demonstrate that the time spent providing information by the Company is subordinate to the time spent gathering information from the attendees. Only presentation materials that are relevant and appropriate to meet the objectives of the advisory board meeting may be used. Generally, all materials used must be reviewed in advance by MLR prior to their use. The venue selection for advisory boards should follow the same criteria as BioXcel speaker programs (see above regarding venue selection for speaker programs).

## 5. INTERACTIONS WITH GOVERNMENT EMPLOYEES

Activities that are permissible when conducted with HCPs who do not work for the government may be prohibited when these same activities are conducted with HCPs who are government employees or officials.

**"**Government Employees**"** in the U.S. may include physicians, pharmacists, other HCPs, formulary decision makers and purchasing personnel employed by government institutions such as Centers for Medicare and Medicaid Services, Department of Veterans Affairs, Department of Defense (including uniformed military personnel), Indian Health Service, National Institutes of Health, Public Health Service, state agencies and state medical centers. These public entities have their own internal rules applicable to the interactions of their employees with the pharmaceutical industry and with respect to meals and gifts, including those requirements set forth in the *Office of Government Ethics' "Standards of Ethical Conduct for Employees of the Executive Branch"* as well as more specific requirements for sales representative interactions with VA facilities, which are set forth in *VHA Directive 1108.10 "Promotion of Drugs and Drug-related Supplies by Pharmaceutical Company Representatives"*. It is important to note that most HCPs outside of the U.S. are employees or officials of foreign government agencies and, therefore, are considered "Government Employees.



### 5.1 Meals and Educational Items for Government Employees

BioXcel Personnel may not provide meals, educational items or anything of value to a Government Employee with the intent of inducing the Government Employee to perform any act, favorable or unfavorable, for BioXcel. Meals and educational items must adhere to the

following requirements:

| MEALS AND EDUCATIONAL ITEMS FOR GOVERNMENT EMPLOYEES | | |
|---|---|---|
| **MEALS** | **EDUCATIONAL ITEMS** | **BOTH** |
| ✓ Meals hosted by BioXcel Personnel must take place at the Government Employee's office or hospital<br><br>✓ The Government Employee must confirm that he/she is permitted to accept meals<br><br>✓ The meal cannot exceed $20 retail value per Government Employee per occasion or $50 retail value per Government Employee in a calendar year<br><br>✓ Light refreshments are permitted when incidental to a scheduled meeting or legitimate educational exchange and do not count toward the $50 cap.<br><br>✓ Not permitted at VA facilities or for VA staff | ✓ BioXcel Personnel must obtain MLR approval prior to use and/or dissemination<br><br>✓ The educational item cannot exceed $100 retail value per Government Employee in a calendar year<br><br>✓ The educational item cannot be primarily created for entertainment, display, or decoration | ✘ Meals and/or educational items cannot be provided with the intent of inducing the Government Employee to perform an act favorable or unfavorable to BioXcel<br><br>✘ Meals and/or educational items cannot be provided on a regular, repeated or recurring basis |



### 5.2 Interactions with Department of Veterans Affairs Employees

Interactions with employees from the Department of Veterans' Affairs ("VA") are stricter than the rules governing interactions with other Government Employees. The rules below apply to

meetings with HCPs who work part-time for the VA when meeting with them at a VA facility. These rules do not apply when meeting with the HCP in the HCP's private office or hospital.

| VISITING A VA FACILITY | |
|---|---|
| **REQUIRED** | **PROHIBITED** |
| ✓ Schedule an appointment before visiting.<br><br>✓ Meet only with the HCP with whom the appointment was made.<br><br>✓ Acquire prior approval from the facility's Chief of Pharmacy Services (or their designee) sixty (60) days prior to conducting an educational program.<br><br>✓ Provide any MLR approved program materials to the VA at least sixty (60) days in advance of distributing (unless VA agrees otherwise). | ✘ Do not provide any food items to VA staff (including volunteers and employees who are not compensated).<br><br>✘ Do not bring food items into the facility for use by non-VA staff (*e.g.*, employees of affiliates).<br><br>✘ Do not include BioXcel name or company logo, or promote a specific medication, on program materials unless approved by VA Pharmacy Benefits Management Service. |



### 5.3 Widely Attended Events

It may be acceptable to offer Government Employees free or reduced admission to all or part of a "widely attended event," including those that provide a meal if the event:

- Occurs in a venue conducive to scientific or educational communication;
- Provides an opportunity for attendees to exchange views or ideas;
- Is attended by a large and diverse group; and
- Is in the interest of the government agency because it will further agency programs and operations.

Government Employees should only receive food, refreshments, instruction and materials as part of a widely attended event if furnished to all attendees as an integral part of the event. For example, gift baskets distributed at the end of an event would not be integral to the event and would, therefore, not be permissible.

### 5.4 Lobbying

Certain BioXcel activities may be considered "lobbying" and subject to significant regulatory oversight on both the federal and state level. These include state laws requiring individuals, including BioXcel Field Sales Personnel, to register as lobbyists and disclose certain lobbying expenditures.

| Lobbying<br>Seeking to influence or encourage the actions, decisions or recommendations of a Government Employee | | |
|---|---|---|
| **State/Local Laws:**<br>• Colorado<br>• Connecticut<br>• Kentucky<br>• Louisiana<br>• Miami-Dade County, Florida | **Includes:**<br>• Negotiating contracts with government agencies<br>• Providing information to government formulary committees<br>• Interacting with state hospital administrators or HCPs. | **Examples:**<br>• Attempting to influence HCPs in a position to make decisions regarding the use of BioXcel products in their facility<br>• Communicating with P&T Committee members to have a drug included on the state's formulary |

BioXcel is committed to complying with all federal and state lobbying laws and has established policies and procedures to govern the activities of BioXcel Personnel who interact with state and federal Government Employees.

### 5.5 Investigations by Government Agencies

All BioXcel Personnel are expected to cooperate with any and all inspections, inquiries and investigations initiated by external government agencies. In connection with any such inspection, inquiry or investigation, BioXcel Personnel should do the following:

- Ask for the agent for his or her credentials;
- Ask to see any documents authorizing the agent to perform the inspection, inquiry or investigation, such as a subpoena or warrant;
- Comply with any validly produced documents; and
- Contact the BioXcel Legal Department immediately.

## 6. INTERACTIONS WITH PATIENTS AND PATIENT ORGANIZATIONS

### 6.1 General

BioXcel may provide support to patient organizations based upon the organization's goals and objectives; reputation; activities; number of patients served; and geographic reach in accordance with BioXcel's policies on grants and corporate giving. BioXcel will respect the independence and values of the organizations and will not engage with – or be perceived as engaging with – patient organizations in a way that undermines their independence or the rules and regulations that govern BioXcel's own activities.

## 6.2 Interactions with Patients/Patient Privacy

### 6.2.1 Patients

BioXcel Personnel may occasionally interact and communicate with patients at patient-focused events. When doing so, the following rules should be followed:

- All communications with patients must be truthful, accurate, balanced and not misleading and must comply with all policies regarding BioXcel Promotional Materials.
- Communicate in a truthful and non-misleading manner about BioXcel's role or involvement with the patient or patient organization, and act ethically and in compliance with applicable laws, guidance and Company policies;
- Respect patient privacy and confidentiality;
- Never provide medical advice or recommendations related to treatment, or interfere in the HCP-patient relationship, and always direct patients back to their HCPs for medical questions;
- Do not use relationships to exert improper influence or coercion or to create the perception of improper influence or coercion on activities or choice of therapy; and
- Do not engage, communicate or interact with pediatric patients or patients under legal guardianship without a signed approval from their legal guardian.

### 6.2.2 Privacy

BioXcel Personnel must not seek or solicit personal information from patients and must safeguard the privacy of any personal information received during patient interactions. BioXcel Personnel should avoid any situation where a HCP may intentionally or inadvertently disclose a patient's protected health information ("PHI") without the patient's signed consent. PHI includes many common identifiers, such as but not limited to, a patient's name, address, birth date, or Social Security Number. BioXcel Personnel must not:

- Seek or accept PHI from HCPs in any form, including written, electronic or oral;
- Review patient charts or other documents that contain PHI, even if requested by the HCP;
- Engage or authorize anyone to engage in the review of PHI; or
- Copy, reproduce, communicate or use any PHI received inadvertently.

Any patient data used in communications must be de-identified, meaning any PHI identifiers must be removed from the patient data.

### 6.2.3 Gifts and Educational Items

BioXcel Personnel may not provide gifts or non-educational items to patients or caregivers unless approved in advance by the Compliance Officer. Gifts and non-educational items may never be used to inappropriately influence a patient or caregiver to choose a BioXcel product or service,

or to choose a particular HCP. Occasional meals, snacks or refreshments may be provided to patients in connection with a BioXcel-hosted meeting or event provided that the meal is incidental to the main purpose of the event. As with HCP meals, such meals must be modest and reasonable based on local standards. No entertainment, gifts or other leisure or social activities should be provided or paid for by BioXcel.

#### 6.2.4 Visiting Medical Facilities

When BioXcel Personnel are in a medical or clinical setting where patients are present, they must follow all applicable facility regulations, restrictions, and guidelines. BioXcel Personnel must also:

- Undergo appropriate training as directed by BioXcel;
- Only be in a clinical setting at the request of and under the supervision of an HCP;
- Be transparent that they are acting on behalf of BioXcel in a technical support capacity;
- Follow all applicable laws and any BioXcel policies regarding patient privacy; and
- Provide notification and receive approval in accordance with the specific medical or clinic setting's credentialing requirements as well as applicable local laws and regulations.

## 7. INTERACTIONS WITH PAYORS

BioXcel is committed to the principle that HCPs should prescribe BioXcel products only when their use is clinically appropriate. BioXcel Personnel, when engaging in promotional discussions with HCPs, should keep in mind that HCPs should make prescribing decisions based on the product's safety, efficacy, and appropriateness for the patient. This reinforces BioXcel's goal of improving patient care and of behaving in an ethical and responsible manner.

BioXcel Personnel who work in Market Access ("BioXcel Market Access Personnel") focus specifically on working with purchasers and third-party payors to facilitate access, coverage, and reimbursement for BioXcel's products and to negotiate contracts with managed care organizations, group purchasing organizations, and other HCPs ("Customers"). In connection with these activities, BioXcel Market Access Personnel may meet and communicate information about BioXcel products with financial decision-makers for these Customers, such as Pharmacy & Therapeutics committees or other assessment committees.

BioXcel Market Access Personnel may not engage in any activity that could be perceived as improperly influencing the independent judgment of a Customer. This includes, but is not limited to:

- Providing a meal or gift that does not comply with BioXcel or the Customer's policies;
- Inviting an HCP or other employee affiliated with a Customer to become a BioXcel speaker, consultant, or member of an advisory board if one reason for the invitation is to influence an upcoming decision about formulary status or coverage of a BioXcel product;

- Offering to provide a grant, charitable donation, or exhibit and display fee if one reason for the offer (payment) is to influence an upcoming decision regarding payment or coverage of a BioXcel product; and
- Linking, either directly or indirectly, financial support from BioXcel with the exercise of the Customer's judgment on a decision related to formulary status or coverage of a BioXcel product.

In addition to interacting with Customers, BioXcel Market Access Personnel may also provide HCPs with factual and objective information regarding product pricing and reimbursement codes related to BioXcel products. BioXcel Market Access Personnel are also permitted to make HCPs aware of available and approved co-pay assistance programs and patient assistance programs (PAP) for BioXcel products. Any and all materials utilized by BioXcel Market Access Personnel with Customers regarding BioXcel product's, pricing, coverage or reimbursement must be approved in advance by MLR.

BioXcel also enters into contracts with various types of Customers to make BioXcel products available on formularies. These contracts may include discounts, rebates and other pricing arrangements that are subject to various rules and reporting obligations. These contracts may be initiated by BioXcel Market Access Personnel only. All Customer contracts must be reviewed and approved by the Legal Department prior to execution by BioXcel and the Customer.



## 8. BIOXCEL MEDICAL AFFAIRS/COMMERCIAL PERSONNEL INTERACTIONS

The role of BioXcel Medical Affairs Personnel is to act as scientific and medical experts to facilitate Scientific Exchange between the scientific community and BioXcel. The role of BioXcel Commercial Personnel is to focus on brand strategy and product promotion. While certain interactions between these two groups is appropriate and necessary, it is important that each of these groups remain functionally independent, not direct or control the activities of the other, or be viewed or treated as an extension of the other function.

### 8.1 Permissible Joint Interactions

#### 8.1.1 Meet and Greets

BioXcel Medical Affairs Personnel and BioXcel Field Sales Personnel may occasionally facilitate meetings to introduce HCPs to one another ("Meets and Greets"). BioXcel Medical Affairs Personnel and BioXcel Field Sales Personnel may only coordinate logistics and jointly meet with HCPs for purposes of initially introducing one another to an HCP with whom they have an established relationship. Meet and Greets should not occur on a regular basis and, after the initial introduction, all future HCP interactions should be conducted separately. If Scientific Exchange, including responding to unsolicited requests, occurs at a Meet and Greet, BioXcel Field Sales Personnel may not participate, either directly or indirectly, in the discussion and should leave the room or, if not possible, be separate from the conversation.

#### 8.1.2 BioXcel Sponsored Clinical Studies

If an HCP expresses interest in serving as a Principal Investigator for a BioXcel-sponsored clinical study , BioXcel Commercial Personnel may let BioXcel Medical Affairs Personnel know there is an interest, but should avoid offering an opinion as to whether the HCP would be appropriate for the trial or otherwise try to influence any decisions.

#### 8.1.3 HEOR Communications

BioXcel Medical Affairs Personnel may support BioXcel Market Access Personnel with the communication of HEOR and other information to payors and formulary committees.

#### 8.1.4 HCP Insights

BioXcel Medical Affairs Personnel may obtain feedback from HCPs and the medical community at large, as needed, and share this information with BioXcel Commercial Personnel to support their commercial and research activities.

#### 8.1.5 Speaker Training

BioXcel Medical Affairs Personnel may conduct speaker training for HCPs contracted by BioXcel Commercial Personnel.

### 8.2 Impermissible Joint Interactions

#### 8.2.1 HCP Interactions

BioXcel Commercial Personnel must not solicit or utilize the assistance of BioXcel Medical Affairs Personnel to gain access to HCPs, or involve BioXcel Medical Affairs Personnel in any planned promotional call activities, including field “ride-alongs” and in-office visits. BioXcel Field Sales Personnel must not participate in any planned activities in which BioXcel Medical Affairs Personnel will:

- Present emerging medical and/or scientific information;
- Discuss off-label information in response to an unsolicited request; or
- Conduct a clinical site visit.

#### 8.2.2 Educational Grants

BioXcel Medical Affairs Personnel shall be involved in the review and approval of medical education and research grants, including making commitments to third parties. BioXcel Commercial Personnel should not be involved in this decision-making to avoid any appearance of influence.

### 8.3 CME Attendance

BioXcel Field Sales Employees may not participate in or attend accredited continuing medical education ("CME") programs at national or international congresses, conferences, symposia or other major medical meetings. BioXcel Field Sales Personnel may, however, participate in promotional exhibits at such events if they take place outside of the educational area of the event. Live promotional presentations or distribution of Promotional Materials must be separate from the CME event.

### 8.4 Booth Activities

When there is a medical booth and a promotional booth at the same event, each booth must be in a distinct area and staffed by appropriate BioXcel Personnel. BioXcel Commercial Personnel may not be present at the medical booth. BioXcel Medical Affairs Personnel may be present at a promotional booth, but may not respond to Off-Label questions or act in a medical capacity at the promotional booth.

## 9. FINANCIAL SUPPORT AND CORPORATE FUNDING

BioXcel provides financial support to third parties in the form of educational grants, sponsorships, exhibits, and charitable contributions. Financial support or corporate funding of any kind should be handled through the applicable BioXcel review process and may not be provided to reward or induce a third party or entity to use, prescribe, purchase or recommend a BioXcel product or to influence the outcome of a clinical trial.

## 10. RESEARCH

### 10.1 Company-Sponsored Clinical Trials

BioXcel-sponsored clinical trials are studies for which BioXcel retains ultimate responsibility for the design, conduct, supervision, regulatory approval and funding of the trial. BioXcel-sponsored clinical trials must ensure compliance with all FDA requirements and be designed with a legitimate research purpose in mind.

Investigators must be selected based on their expertise in the applicable therapeutic area and ability to meet study requirements, adhere to all applicable laws and regulations, maintain required data, and meet other research-related criteria. BioXcel may not select investigators as a reward for prescribing behavior or based on their ability to generate business for BioXcel.

Compensation arrangements with investigators and institutions must be consistent with fair market value, be designed to avoid conflicts of interests, and comply with all BioXcel policies. BioXcel may not provide compensation to investigators in stock or stock options or tie compensation to the outcome of the trial.

Compensation to research subjects should be consistent with guidance from the Office for Human Research Protections, and the PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results. Financial compensation offered to subjects in clinical trials should be:

- IRB-reviewed and approved;
- Disclosed in the informed consent form;
- Calculated based on the nature of the research subject's actual or anticipated costs of participation (*e.g.*, parking or travel);
- Not wholly contingent on completing the trial (*e.g.*, prorated per visit); and
- Documented in a written clinical trial agreement between BioXcel and each investigator/site.

### 10.2 Medical Affairs Employees Interactions with HCPs

BioXcel Medical Affairs Personnel may approach qualified HCPs regarding their potential interest in participating in a BioXcel-sponsored clinical trial if they are bona fide candidates for such participation based on their training, experience, patient base, institution, and other relevant factors. During BioXcel-sponsored clinical trials, BioXcel Medical Affairs Personnel may:

- Inform HCPs on study details when such information is requested;
- Submit names of interested investigators to BioXcel Clinical Development/Clinical Operations for evaluation;
- Accompany Contract Research Organization staff on site engagement visits and respond to questions as needed;
- Make presentations at site visits on publicly available study details or other public domain information; or
- Refer operational questions and communicate concerns or field insights directly related to a BioXcel-sponsored study to BioXcel Clinical Operations.

Clinical investigators are subject to all BioXcel policies on meals, travel, and venue.

### 10.3 Communication of Clinical Trial Data

BioXcel is committed to the timely and appropriate disclosure of meaningful results of Company-sponsored clinical trials of its marketed and investigational products. All Company-sponsored clinical trials of BioXcel products or product candidates must be registered on clinicaltrials.gov.

Any communications that discuss clinical trial data, should generally include information about the regulatory approval status of the BioXcel product, applicable indication, study design, statistical significance of the study endpoints, dosing regimen, patient population, duration of treatment, and other material information bearing on the overall quality of the study. Communications should include balanced information, including the study limitations and safety considerations and should disclose BioXcel's involvement in the case of BioXcel-sponsored

studies. MLR must review and approve all such communications prior to dissemination by BioXcel Personnel.

### 10.4 Investigator Initiated Trial

BioXcel provides grants to HCPs to conduct investigator initiated Trial ("IIT"). This type of clinical trial is initiated and conducted independently by an independent investigator for which BioXcel supplies financial support, the study drug, and/or equipment (*i.e.*, BioXcel does not serve as the sponsor of the research). BioXcel only supports IITs undertaken with a *bona fide* scientific purpose to answer a meaningful medical or scientific question of legitimate interest to BioXcel. BioXcel involvement in the IIT is limited to providing financial support, study drug, and/or equipment and BioXcel is not responsible for the design and execution of the IIT.

Requests for IIT support may not be judged on the basis of past, present or future intention or willingness to prescribe, use or recomment BioXcel products, and all applications will be assed according to the merits of the study in terms of the quality of the proposed clinical trial and in accordance with BioXcel policies and procedures.

## 11. PUBLICATIONS

BioXcel Medical Affairs Personnel oversee the publication planning for BioXcel products and research initiatives. BioXcel Commercial Personnel may not be involved in the preparation, planning or content development of publications. Any questions relating to the Company's publication process should be referred to BioXcel Medical Affairs Personnel.

## 12. QUALITY AND PATIENT SAFETY

BioXcel is committed to patient safety in all of its activities. BioXcel carefully assesses the risks and benefits of its products before and after they are brought to market and works with the appropriate regulatory authorities to provide accurate and complete information about indications and safety of its products. BioXcel is also committed to developing and manufacturing the highest quality products in accordance with Good Manufacturing Practices (GMP) and all applicable laws, rules, regulations and standards.

FDA regulations require that BioXcel monitor and report all adverse events and product complaints.

- An "adverse event" is an unwanted or harmful reaction experienced following the administration of a drug or a combination of drugs. This includes reports of lack of effect, no efficacy or the product "not working".
- A "product complaint" includes any oral, written or verbal communication that alleges deficiencies related to the identity, strength, quality or purity of a distributed product.

If BioXcel Personnel become aware of an adverse event or product complaint, they must immediately report it within one (1) business day of learning of the event or complaint. When reporting an adverse event or product complaint, BioXcel Personnel should provide all available information, including where possible:

- Reporter's name, occupation, institution, phone number, email address;
- Patient information, initials, age/age group, gender;
- BioXcel Product (Drug) Name, Strength/Dose, NDC #, Lot Number, Expiration; and
- Description of adverse event and/or product complaint, regardless of causal relationship ("I don't think it's related, but…"). Use the terms of the reporter verbatim and do not paraphrase.

Additional information about safety monitoring can be obtained from the Pharmacovigilance and Drug Safety Department.

## 13. PRESCRIBER DATA.

Prescriber data refers to data that identifies the prescribing practices of individual HCPs. Prescriber data allows BioXcel to analyze the prescribing practices of HCPs and to customize its marketing communications strategies accordingly. BioXcel permits the appropriate use of non-patient identifying prescriber data subject to state laws that prohibit or restrict its use.

Prescriber data may be used for the following purposes:

- Providing safety and risk information to prescribers of a BioXcel product;
- Conducting research activities;
- Complying with FDA-mandated risk management plans;
- Tracking adverse events of BioXcel products; and
- Creating marketing plans targeted to HCPs who would benefit from information about a particular BioXcel product.

BioXcel has developed specific policies for the collection, use and security of prescriber data. Please consult those policies to ensure that you conform with all requirements and restrictions for use of prescriber data.

## 14. DRUG SAMPLING PROGRAM

Prescription drug samples are units of prescription products that are given free of charge to HCPs for use with their patients to allow HCPs to become more familiar with its products, and thereby make better informed prescribing decisions. The Prescription Drug Marketing Act ("PDMA"), as well as various state laws and regulation regarding prescription drug samples, set forth specific requirements and restrictions with respect to the provision of drug samples to HCPs. Prescription drug samples may never be provided in exchange for new or potential business, as gifts, as rewards for previous purchases, as a substitute for a discount, for use in clinical trials or research, or for any purpose other than free distribution to patients.

BioXcel is committed to complying with all federal and state drug sampling laws. At this time, BioXcel is not making prescription drug samples available and has not yet established comprehensive policies and procedures to govern the distribution of prescription drug samples by BioXcel Personnel. Accordingly, BioXcel Personnel may not, at this time, distribute prescription drug samples.

## 15. TRANSPARENCY AND DISCLOSURE OBLIGATIONS

BioXcel is committed to tracking and reporting payments and other transfers of value provided to HCPs as required by applicable federal, state and local laws. BioXcel Personnel interacting with or engaging HCPs are responsible for ensuring that any compensation, travel, meals, or other items of value provided to the HCP or a Healthcare Organization, whether directly or through a vendor, are appropriately documented in compliance with applicable BioXcel policies and procedures and uploaded to the appropriate electronic system for the type of spend in accordance with BioXcel policy and procedure.

To help confirm that BioXcel submits accurate and complete information for transparency purposes, all BioXcel Personnel involved in the transfer of value process are required to maintain all books, contracts, records, and other documentation for a period of at least five (5) years from the date of payment or other transfer of value transaction.