Quick Reference Guide

Policy on Interacting with Healthcare Professionals

IROKO PHARMACEUTICALS, LLC

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Quick Reference Guide

This Quick Reference Guide reflects a summary of the policies and rules set forth in the Iroko Policy on Interacting with Healthcare Professionals Handbook. All of your day-to-day responsibilities should demonstrate our commitment to ethical conduct. Be sure that everything you do reflects our shared commitment to patients and Iroko's values, including:

Integrity **"Doing the right things, the right way, every time"**

Teamwork **"Collaborating in good faith"**

Accountability **"Taking personal responsibility"**

Excellence **"Being your best"**

It is the responsibility of every Iroko employee and agent who engages in the activities described in this Quick Reference Guide to be knowledgeable about and comply with Iroko's policies. The Company takes violations seriously and failure to comply may result in disciplinary action up to and including termination, so it is important to know the policies and comply accordingly. If you have any questions regarding the rules, practices, and activities described in this Quick Reference Guide, please feel free to contact the Legal Department or the Compliance Office.

Specific Interactions Covered in this Quick Reference Guide:

Definitions

For the purposes of this Quick Reference Guide:

"Commercial Colleague"	means any member of Iroko's Sales or Marketing department regardless of level within the Company.
"Healthcare Professional (HCP)"	means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities provides healthcare services or may prescribe, recommend, purchase, supply, or administer a pharmaceutical product for human patients. This means that Iroko broadly defines HCP to include those persons who directly interact with patients or have a role in patient diagnosis or treatment. Our broad definition of HCPs includes persons such as medical students, members of drug formulary committees, health plan administrators, and benefit managers; and it also includes entities such as physician practice groups, hospitals, nursing facilities, and clinics. We may refer to these entities as healthcare organizations (HCOs). The definition of an HCP may differ in certain contexts, particularly, for example, how various states define HCPs. We have designed our systems to take these variances into account where these differences are relevant.
"IFPMA Code"	means the International Federation of Pharmaceutical Manufacturers and Associations' Code of Practice applicable to the promotion of medicines and interactions with the healthcare community.
"IRC"	means Iroko's Review Committee as described in MA-003-02 or local copy approval SOP.
"PhRMA Code"	means the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals relating to the interactions with healthcare professionals in the marketing of prescription pharmaceutical products.
"Product Promotion"	means any activity undertaken, organized or sponsored by Iroko or by a vendor engaged by Iroko which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of Iroko products through all methods of communication, including the internet.

Please refer to the *Policy on Interacting with Healthcare Professionals Handbook* for additional definitions.

1. Overview of Relevant Laws and Regulations

The following table summarizes key aspects of the: i) Federal Anti-Kickback Law; ii) the Food, Drug and Cosmetic Act; and iii) the Civil False Claims Act.

Please refer to the *Policy on Interacting with Healthcare Professionals Handbook* (§1) for additional information and for summaries of additional laws and regulations particularly influencing the pharmaceutical industry.

Healthcare Law	Description
Federal and State Anti-Kickback Laws	Healthcare treatment decisions should not be motivated by personal gain or enrichment. Federal and state anti-kickback laws prohibit improper influences by making it a criminal and/or a civil offense to solicit, pay, or offer anything of value to induce someone to purchase, prescribe, or recommend a product that is reimbursed under federal or state government healthcare programs (e.g., Medicare or Medicaid). **For example, anti-kickback laws prohibit:** • Providing a gift to an HCP to influence the prescribing, dispensing, or recommending of pharmaceutical products; or • Paying for the consulting services of an HCP or other customer at a fee above the reasonable, fair market value for such services.
Food, Drug, & Cosmetic Act	The FDCA is a set of laws giving authority to the FDA to oversee the safety of food, drugs, and cosmetics, including advertising and labeling. Any materials (whether in print or electronic form) used to promote our products – including all visual aids, brochures, journal advertising, promotional programs and other sales aids – must include only claims about the product that are: 1) consistent with that product's labeling; 2) accurate and not misleading; and 3) capable of substantiation – meaning appropriately supported by scientific evidence.
Civil False Claims Act	You must not knowingly submit or cause someone to submit a false or fraudulent claim to the federal government to obtain payment. Off-label promotion can be a basis for a false claim allegation by the government in that the government could argue that off-label promotion by the pharmaceutical company "induced" another party to submit a false claim.

2. Sales Presentations and Product Promotion

Our relationships with HCPs are highly regulated, are intended to benefit patients, and are intended to enhance the practice of medicine. Our interactions with HCPs should be focused on informing them about products and providing scientific and educational information.

All information disseminated through Iroko's promotional activities must be:

1) Consistent with the product's FDA-approved package insert and other labeling, or "on-label;"
2) Fair and balanced with respect to efficacy and safety information;
3) Truthful and not misleading; and
4) Delivered to HCPs who are reasonably likely to prescribe — or to patients/caregivers who are interested in — Iroko products for their approved use.

This means:

On-label promotion

- Only information and materials that have been approved for promotional use may be used or distributed in connection with product presentations. The Iroko Review Committee (IRC) ensures that promotional materials are consistent with the product's package insert, are truthful and not misleading, and are appropriate for use with the HCP or patient community for which they were created. Federal regulations require that Iroko file all promotional materials with the FDA at the time of first use with any customer.
- Only discuss approved products and indications. Do not discuss new products or indications until approved by IRC.
- Sales presentations must be made to appropriate HCPs.
- Always give a fair and balanced presentation of the benefits and risks of a product.
- Never engage in actual or perceived quid pro quo. Quid pro quo is Latin for "this for that."

Promotional Materials, Reprints, and Other Items

- Only use Iroko-approved materials. Never use materials that you have created or altered in any way.
- All items (such as reprints, textbooks, etc.) provided to HCPs must be educational and IRC-approved.
- Payments in cash or cash equivalents (such as gift cards) must not be provided or offered to HCPs.
- The PhRMA Code prohibits pharmaceutical companies from offering non-educational items such as pens, pads, mugs, etc. to U.S. HCPs or members of their staff, even if the items are practice-related and of minimal value. Therefore, none of these items may be offered or provided to U.S. HCPs.
- The IFPMA Code permits pharmaceutical companies to offer items of medical utility provided that such items are not banned under the Codes of Practice for the local country, they are of modest value (as defined locally by each individual country that is a member of IFPMA), and they are beneficial to enhancing the provision of medical services and patient care. Therefore, any such item offered to non-U.S. HCPs must be strictly in accordance with local requirements.

Comparative Statements

- All statements must be consistent with the product's package insert, truthful and not misleading.
- You may only make comparative claims that appear in your approved product promotional materials. The FDA considers promotional materials or claims to be false and misleading if they state or suggest that a drug's safety or efficacy is comparable or superior to that of another drug's without "substantial evidence" to support such statements or suggestions. "Substantial evidence" in the context of comparative claims generally means two adequate, well-controlled studies comparing the two drugs head-to-head using comparable dosage regimens. In some instances a single, large, well-controlled study may suffice if first approved by FDA.

Interactions with Pharmacy Network Partners

- Iroko partners with certain direct-to-patient (DtP) pharmacies as well as certain independent/ retail pharmacies through the IrokoCares™ patient access program. Each pharmacy network partner ("PNP") has a dedicated point-of-contact with whom field sales colleagues may interact.
- Engagements with PNP contacts are governed by Iroko promotional standards.
- Field sales colleagues are permitted to share most HCP-specific information with their PNP contact, including information such as which NSAIDs the HCP typically prescribes, the HCP's utilization of the pharmacy, and the HCP's perception of pharmacy performance and service levels. However, colleagues must remain mindful that HCP prescription data is Company confidential information and colleagues must not disclose an HCP's specific prescription data to their PNP contact.
- Field sales colleagues are not permitted to request pharmacy reports from the PNP due to the unfiltered nature of reports from the pharmacy. If you believe that additional or different pharmacy data is needed, please let your Area Vice President know, who will in turn work with the appropriate internal colleague to answer your request.
- Field sales colleagues may invite PNP contacts to attend in-office meetings with the HCP during which the PNP may review his/her pharmacy process and procedure. All product information conveyed during the sales presentation must be delivered by Iroko personnel in accordance with Iroko policy.
- If any unsolicited question or request about off-label information or unapproved clinical data arises, the field sales colleague must refer the question or request to Iroko Medical Information.
- Remember, it is important that you do not request or collect Sensitive Personal Information (SPI), such as personal information about a patient's physical or mental health, in your interactions with your PNP contacts. Avoid situations likely to lead to the inadvertent disclosure of SPI.

Unsolicited Requests for Off-label Information

- You may not initiate discussions with HCPs about off-label information concerning an Iroko product or a competitor product.
- You must not encourage or solicit HCPs to request off-label information.
- If you receive an unsolicited question or request about off-label information or unapproved clinical data, you must forward the request to Iroko Medical Information or ask the HCP to directly contact Iroko's Medical Information.

Use of Social Media

- Iroko may be held accountable for statements and posts of employees or agents, as well as paid or authorized communications. Social media should never be used in a way that violates any Iroko promotional policies or legal or regulatory obligations.
- You are prohibited from discussing any Iroko product, business plan, research, strategy or other business-specific details in any social media forum in a way that could be regarded as advertising or promoting a prescription product or otherwise disclosing non-public information.

Adverse Events

- We all have a role to play to help Iroko deliver on its commitment to improve human health. One of your most important responsibilities is to inform the Company of any adverse events (AE) or product quality complaints. We are all required to report to Medical Affairs any AE that may be associated with the use of our products. Immediately or, at the latest, within 24 hours of becoming aware of an AE, information must be reported, in accordance with Company policies, by faxing a report to +1-877-746-8937 or by calling +1-877-757-0676. Product quality complaints may also be reported by calling 1-877-757-0676.

Medical Information
Phone: 1.877.757.0676
Email: info@irokomedinfo.com
Fax: 1.877.746.8937

Adverse Event Reporting
Within 24 hours of becoming aware...
Phone: 1.877.757.0676
E-mail: info@irokomedinfo.com
Fax: 1.877.746.8937

Use of HCP Prescribing Data

- The American Medical Association (AMA) administers a program that allows physicians to opt out of having their prescriber data released to pharmaceutical sales representatives.
- Field sales colleagues must not use aggregate information provided to them to attempt to "reverse engineer" the prescriber data of an HCP who has opted out.
- HCP prescription data may only be used in a professional and responsible manner and must never be used to badger, embarrass, harass, intimidate, pressure, coerce or punish HCPs in any way.
- HCP prescription data is treated as Company confidential information. Field sales colleagues that know or learn of an HCP's prescription data must not disclose that information to any person outside of Iroko and must take appropriate precautions to ensure the privacy of such information. Failing to do so or misusing the data may result in disciplinary action.

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3. Gifts, Entertainment, Promotional Aids and Educational Items

Iroko is committed to ensuring that interactions with persons or organizations in a position to purchase, prescribe, or recommend Iroko products are both lawful and consistent with the highest standards of ethics and good business practices. This spirit guides the Company's policy on the provision of gifts, meals, and entertainment, which incorporates, among other guidance, the *PhRMA Code* and *IFPMA Code*, Guidance by the Department of Health and Human Services Office of the Inspector General, and the California Comprehensive Compliance Program Law. Additionally, several states have enacted laws that limit or prohibit gifts, meals, or entertainment to HCPs, entities, and/or state employees.

Iroko colleagues must not offer or provide anything of value with the intent of directly or indirectly influencing or encouraging the recipient to purchase, prescribe, or recommend an Iroko product, or as a reward for previously doing so.

Where permissible under this policy, things of value must be modest and provided only on an occasional basis.

- Payments in cash or cash equivalents (such as gift cards) must never be provided or offered to HCPs. Gifts for the personal benefit of an HCP (such as sporting or entertainment tickets, electronics items, etc.) are never to be provided or offered.
- No entertainment or other leisure or social activities should be provided by any Iroko colleagues (either directly or indirectly) to HCPs.

Many countries as well as various States in the U.S. restrict the types of items that can be provided to HCPs. It is important that any item intended to be provided to HCPs be first approved by IRC. Following are examples of some items that are permitted and examples of items that are restricted:

	Examples	Permitted or Restricted
Promotional Material Created by Iroko	Examples include: Leave Behinds, Patient Education Materials, etc.	Permitted: Must be approved by IRC.
Promotional Aids	Examples include: Inexpensive pens or notepads	Restricted: Promotional Aids must not be provided to U.S. HCPs because such items are prohibited by the PhRMA Code.
Educational Items and Items of Medical Utility	Examples include: Anatomical models, textbooks, reprints, journal subscriptions, etc.	May be permitted if: - Provided in accordance with local laws and regulations, of modest value, designed primarily for the education of patients or HCPs, and are approved by IRC.

4. Meals Policy

Guidance for Field Sales Colleagues

Field sales colleagues may offer a meal in connection with a Sales Presentation only if:

- The Sales Presentation provides scientific or educational value
- The meal provided complies with state law requirements/restrictions
- Meals may only be provided on an occasional basis and must be:
  - **Limited to in-office or in-hospital/clinic settings unless in connection with an approved Speaker Program**
  - Modest and reasonable according to local standards (U.S. field sales colleagues should not exceed $25 per person inclusive of tax and tip)
  - Devoid of any entertainment or recreational activity
  - Provided in a manner conducive for informational communication
  - Limited to HCPs and appropriate staff; no spouses or other non-staff guests are permitted
  - Provided in the presence of the field sales colleague (i.e., offering a take out meal is not permitted)
- The disclosable value of a meal is calculated by taking the total cost of the meal and dividing it by the number of actual participants partaking in the meal. Each participant in the meal must be appropriately documented in the expense reporting system.

Guidance for Headquarter Colleagues and Colleagues at the Vice President-level or Higher

The policy rules for field sales colleagues apply to Headquarter colleagues or colleagues at the VP-level or higher with the exception that:

- There must a legitimate business reason for hosting the meal (i.e., legitimate educational presentation or business discussion consistent with the colleague's role)
- The meal need not be limited to the in-office or in-hospital setting; however, it is nevertheless important that it complies with state or local law requirements/restrictions
- The policy limit on the value of the meal with U.S. HCPs is higher; a meal that includes U.S. HCPs must remain modest by local standards and in no event may it exceed $130/person, including tax and tip.

What is considered a meal

For purposes of Iroko policy, any type of food or beverage is considered a meal and, thus, may not be provided by field sales colleagues outside of an office, clinic, or hospital setting unless in connection with a Speaker Program.

5. Federal and State Transparency Reporting and Restrictions

In addition to international and federal reports, there are ten (10) other jurisdictions where Iroko may be required to make disclosures/reports or place caps on spend:

Jurisdiction	Disclosure Obligation
International	There are recently enacted regulations that may potentially impact Iroko's obligations to disclose payments made to HCPs outside the U.S., including, for example, the French Sunshine Act and the EFPIA HCP/HCO Disclosure Code.
Federal	The Sunshine Act requires Iroko to report payments and transfers of value from field sales colleagues, as well as those made by headquarter personnel, including Medical Affairs and Research and Development. The law extends to any payment or transfer of value provided to another party at the direction of or on behalf of a physician or teaching hospital, and any payment or transfer of value provided to a third party that is then passed through to a physician or teaching hospital when Iroko knows the identity of the physician or teaching hospital.
California	Iroko has publicly committed to a $2500 annual aggregate spending limit for an HCP licensed in California for all meals and educational items that are permitted under this policy for those HCPs. This includes meals or educational items provided by Headquarter, International, and field sales colleagues, in-office and out-of-office meals, and meals that are provided to the attendees of speaker programs. Payments for legitimate professional services, e.g. consulting, are excluded from the company's limit, provided they are permitted under Iroko policy and consistent with fair market value for those services.
Connecticut	Beginning July 1, 2017, Iroko must provide annual reports on fees or transfers of value provided to Advance Practice Registered Nurses engaged in "independent practice" in the state.
District of Columbia	All representatives must secure a license to legally detail in person in D.C. and Iroko must report certain product marketing costs (certain employee total compensation figures are counted in the costs). Iroko must also report marketing expenditures over $25 to HCPs licensed to provide healthcare in the District. Members of the D.C. Medication Advisory Committee must not receive gifts, including meals or remuneration, for speaking or consulting, no matter how nominal the value.
Florida (Miami-Dade County)	Iroko must report "lobbying" payments to HCPs affiliated with a Jackson Health System facility or other county-funded facility.
Maine	Iroko must pay an annual fee if Iroko has any sales, sales representative, promotional activity, rebate agreements with the state or if Iroko products are provided to Maine residents through MaineCare (Medicaid) or Maine's Elderly Low-cost Drug Program.
Massachusetts	Iroko must track and annually report expenditures over $50 to Massachusetts "covered recipients," regardless of where the event takes place, to the extent such expenditures are not reported under the Federal Sunshine Act for the applicable "covered recipient."
Minnesota	Iroko must report certain payments if they total $100 or more per year and are made to NPs, PAs, and dental therapists. The Minnesota Gift Ban Law prohibits gifts in excess of $50/year/HCP in the aggregate among all Iroko colleagues. Therefore, Iroko policy prohibits gifts to MN-licensed practitioners. Iroko policy prohibits meals to MN practitioners, including in-office meals and nominal food and beverage except in connection with the following permitted types of projects. Iroko policy prohibits engaging MN practitioners as paid consultants, except for the following types of projects: • R&D or clinical projects • Outcomes research • Medical publication-related projects • Speaking and Speaker training * **MN-licensed practitioners must not be engaged to participate in Iroko Advisory Boards.**
Nevada	Nevada Marketing Code of Conduct requires companies to adopt a marketing code of conduct and make a declaration of compliance if requested.
Vermont	Vermont prohibits all HCP meals, including in-office meals and meals of nominal value (there is a limited exception for: (i) bona fide service contracts and (ii) refreshments or other snacks at a booth at a convention/congress). Vermont also prohibits paid market research surveys involving VT licensed HCPs. The restriction applies whether the survey is conducted directly by Iroko or through an independent third-party survey research organization. Iroko must report certain HCP expenditures, as well as samples, coupons and vouchers, to VT. Iroko must also self-report any violations of the Vermont Code.
West Virginia	Certain HCP and advertising expenditures must be disclosed.

State Law Restrictions

Almost all states have restrictions on interactions with state employees (including HCPs employed by state institutions). Consult with the Legal or Compliance Department if you have any questions concerning restrictions for a particular state employee. A summary of the most significant state restrictions is provided below.

Jurisdiction	State Law Restriction
Colorado	State employees may not receive anything of value worth more than $50 from a company (as a whole, not by employee).
Louisiana	State employees are prohibited from performing certain compensated services for pharmaceutical companies. State employees have a $50 cap on food, drinks, and refreshments provided during a single event.
New York	State and local employees are prohibited from receiving gifts.

6. Medical Convention Exhibits and Displays Colleague Attendance at Accredited Scientific Events

***No Iroko colleague (whether in Sales, Medical, or other functional area) can provide any food (not even nominal food/beverage) or other support in connection with an accredited continuing medical education activity** (ACCME, ACPE, or ANCC). Even if you are offered time to promote while providing a meal to attendees at an accredited medical education conference, you must decline that opportunity since any type of financial support for accredited continuing education, including payment for event expenses or meals, can only be funded through an independent professional education grant. Requests for grants supporting accredited events should be sent by the requestor directly to Iroko's Chief Medical Officer.

7. Interactions with Iroko Medical Science Liaisons

Iroko Medical Science Liaisons (MSLs) are field-based Medical Colleagues with expertise in the Medical Affairs functions. MSL responsibilities are focused on medicine development and include communicating scientific and medical information through scientific exchange. MSLs engage almost exclusively in non-promotional activities.

In very limited circumstances, MSLs may engage in activities that are governed by promotional standards. These limited circumstances are only: (i) helping to train commercial colleagues or Speakers, and (ii) presenting to Pharmacy & Therapeutic Committee members or managed care formulary decision-makers. In each of these cases, MSLs must use only IRC-approved materials.

MSLs must not:
- Conduct sales calls with field sales colleagues
- Use their relationship with HCPs as a way to provide access to those HCPs for field sales colleagues
- Provide billing/coding services to HCPs
- Assist HCPs (including suggesting the content for forms) in obtaining coverage and must not state or imply that a formulary status makes an Iroko product more effective or safer than a competitor product
- Make patient-specific treatment recommendations or otherwise provide patient-specific medical advice

Relationships/Interactions with other Iroko Colleagues

The decision to involve an MSL in promotional activities can be made only by Iroko's Chief Medical Officer. For similar reasons, meetings among MSL colleagues and commercial colleagues (whether HCPs are also invited or not) must be limited and approved in advance by the Chief Medical Officer and the Compliance Office. Moreover, it is not appropriate for field sales colleagues to have regular, scheduled internal interactions or meetings with MSLs.

All unsolicited requests for off-label information must be sent to Medical Information and may not be forwarded directly to MSL colleagues.

8. Advisors and Consultants

Contract Requirements: Iroko must execute written agreements with its consultants, which must be approved by the Legal Department.

The agreement must describe the scope of work, the consultant fees (which must be based on fair market value), and consultants must contractually agree to disclose their consultant relationship as well as agree to adhere to the disclosure requirements of any healthcare institution or other organization with which the consultant is affiliated. Because of the inherent kickback risk that HCP consulting arrangements pose, a **Business Need Form (BNF)** is used to document that there is **a legitimate need** for proposed consultant services. All BNFs must be approved by Compliance and Medical Affairs.

Iroko may provide compensation to HCP consultants in amounts constituting fair market value, as well as reimburse reasonable expenses associated with consulting activities. However, since these interactions potentially implicate anti-kickback laws and other U.S. and international anti-corruption laws, it is important to establish that a proposed consulting relationship is bona fide prior to engaging the consultant, as well as follow the other requirements set out in this Policy.

An HCP consulting arrangement is permissible as long as*:

- There is a legitimate business need for the services;
- The consultant(s) is selected based on his or her expertise and knowledge and not to gain access or to influence prescribing habits;
- The number of consultants selected is supported objectively and is appropriate to the business need;
- A written contract is executed prior to the provision of services that specifies the nature of the services and the basis of payment for those services;
- The term of the agreement is for at least one year;
- The services are provided as outlined in the written contract; and
- Any compensation does not exceed the Iroko-approved fair market value rate. In rare cases, exceptions to the Iroko-approved fair market value rate may be granted only with appropriate documentation and prior approval of the Chief Medical Officer and General Counsel.

The objective in entering into a consulting arrangement with an HCP must never be to:

- Establish or improve Iroko's relationship with the HCP;
- Gain or improve access to the HCP;
- Reward past prescribing or induce future prescribing; or
- Influence formulary decision making.

All consulting agreements must be reviewed and approved by the Legal Department prior to execution. HCP consultants who are members of a formulary or clinical practice guidelines committee must disclose to that committee the existence and nature of their relationships with Iroko. This disclosure requirement extends for at least two years beyond the end of a consulting arrangement.

Additionally, Iroko colleagues must ensure that:

- The consultant's qualifications meet the identified business need;
- The consultant does not appear on the FDA Debarment List, the OIG/GSA List of Excluded Persons, or Iroko's screening list for state discipline and FDA Warning Letters. In addition, Minnesota-licensed HCPs may only serve in very limited capacities as consultants, in accordance with the requirements set out above in Section 5. Also, non-U.S. HCPs must be screened to ensure they do not appear on U.S. Federal Restricted Party screening lists (or other similar international lists of sanctioned persons).
- It is documented how the feedback/advice obtained from the HCP consultant was used for a legitimate business need.

*For non-HCP consulting arrangements, please consult with the Legal Department for contracting requirements.

9. Speaker Programs

A Speaker Program is a promotional activity provided by Iroko in which an approved Speaker, generally an external HCP under contract with Iroko, presents information on products, disease states or other healthcare topics to a group of HCPs and/or other appropriate attendees. Promotional speaker programs allow Iroko to present experts to educate HCPs about our products and other relevant topics.

The FDA considers HCP speakers to be representatives of the pharmaceutical company for whom they are speaking on behalf. Thus, **Iroko is responsible for the content and conduct of its Speaker Programs.** This includes all information presented by the Speaker, any payments related to the program, as well as the venue and other details of the event. **All Speaker Program materials (including presentation, agenda and slide deck materials) must be approved in advance by IRC.**

Speaker Selection and Training

Through the Speaker Program, Iroko retains qualified HCPs to speak on the Company's behalf concerning its products and the diseases that they treat, consistent with the products' on-label uses and disease awareness guidelines.

The Marketing Department is responsible for selection and retention of Speakers. The following criteria are applied to individuals engaged as Speakers:

- The Speaker must be a licensed HCP who has appropriate expertise and acceptable public speaking skills.
- Prospective Speakers must not be debarred or excluded by the FDA or OIG, and must meet all the other screening requirements that pertain to HCP Consultants.
- Speakers must not be selected based on an explicit or implicit understanding, hope, or desire that they will prescribe, purchase, or recommend Iroko products as a result of participation in the Speaker Program.
- Speakers (and HCP consultants) who are members of a formulary or clinical practice guidelines committee must disclose to that committee the existence and nature of their relationships with Iroko. This disclosure requirement extends for at least two years beyond the end of a speaker arrangement.
- To remain active in the Speaker Program, each Speaker must attend a training session at least once per year and must provide at least two promotional lectures per calendar year.
- The total annual compensation, including reimbursement for travel/lodging and meals while providing speaking services, must not exceed the per HCP maximum established by the Company.

Scheduling and Conducting a Speaker Program

All Speaker Programs are scheduled by Iroko's trained third-party vendor. All Speaker Program invitations, arrangements/logistics and costs must be handled by the third-party vendor.

At least one Field Sales colleague must attend the entirety of each product-related Speaker Program. The Field Sales colleague has responsibilities in relation to a Speaker Program to ensure that the Speaker has reviewed Iroko Speaker policies and the approved slide deck, that attendance at the program is captured and also monitored for appropriate attendees, that the program is clearly introduced as a program sponsored by Iroko, and ensure that the Speaker appropriately limits and narrowly tailors his response should an unsolicited question regarding an off-label topic arise.

10. Privacy

Personal Information (PI) includes any information that alone or in combination with other data can be used to identify a person. Sensitive Personal Information (SPI) is a subset of Personal Information which includes personal information about a person's physical or mental health (e.g., a person's medical history, physical or mental condition, diagnosis or treatment or the identity of the person's healthcare provider or health insurer).

Regardless of the circumstances under which PI is disclosed, when an individual chooses to share such information with a person they trust, they generally expect the person to hold that information in confidence and to keep it secure. Iroko respects this expectation and is committed to appropriately protecting Personal Information.

It is important that you do not request or collect Sensitive Personal Information for any reason unless you have specific approval to do so. For example, you may not review charts or documents containing SPI or engage in, fund, or authorize others to review SPI. Avoid situations likely to lead to the inadvertent disclosure of SPI, such as private conversations between HCPs and patients.

Any suspected breach of security of PI or SPI should be immediately reported. Lost or stolen computers or other devices should be reported to your manager and the IT Security Officer at 267-546-3456. Any incidents of potential unauthorized access to Iroko data should be reported to the IT Security Officer as well as the Legal Department.

11. Prescription Drug Samples

Iroko provides HCPs with free pharmaceutical drug product samples to give to patients so that they can evaluate the efficacy and tolerability of our products for the patient before filling a prescription. Samples also provide HCPs an opportunity to become familiar with a drug and its properties, thereby enhancing their ability to make appropriate prescribing decisions. The distribution of samples is highly regulated under federal and state law, and the misuse of drug samples can have severe implications.

The Prescription Drug Marketing Act of 1987 (PDMA) is the key federal law governing the distribution of drug samples.

Following are key points to ensure compliance:

- It is illegal to sell, purchase, or trade, or offer to sell, purchase or trade, samples. Samples may be provided only to licensed HCPs eligible to receive samples and only if they are expected to distribute them for free for on-label use by their patients. Iroko is required to independently verify HCP licenses before they may provide samples to such HCPs.
- The amount of samples allocated must be based on the expected on-label use of the product. Samples must not be provided to HCPs in quantities that may appear to be intended as an inducement to use Iroko products (i.e., a kickback). Providing samples in quantities or dosages based on off-label use is not permitted.
- Individual sample units cannot be altered in any way either before or after they are delivered to an HCP.

- Only licensed HCPs authorized by their states' laws to receive and prescribe medications may sign a request for samples. Iroko policy requires field sales colleagues to personally witness the signature on every sample request.

Pharmaceutical companies and individuals have been charged under the False Claims Act and the anti-kickback laws, and fined hundreds of millions of dollars, for encouraging HCPs to bill government programs for samples. For this reason, HCPs must confirm their understanding and acceptance of the fact that samples "cannot be sold, traded, bartered, returned for credit or utilized to seek reimbursement" by signing either electronically or via paper form that they attest to this fact. This attestation is included on the Iroko Sample Request Form.

Iroko must report certain data related to sample distribution to Vermont and to the FDA, pursuant to the Sunshine Act provisions of the Affordable Care Act.

12. Publications

As part of our commitment to publishing the results of Company-sponsored patient research studies, Iroko supports the publication of manuscripts associated with these studies. Iroko also supports other types of publications, such as abstracts, congress presentations and review articles.

First and foremost, Iroko publications are not marketing tools. While a publication may eventually be used in a promotional context, the planning and development of a publication must be true to the data and independent of commercial strategy or messaging. Second, Iroko colleagues must ensure that any engagement of HCPs to author or produce publications does not give rise to inappropriate financial relationships or influence. Importantly, the process by which authors are selected and compensated, if not structured appropriately, may violate the federal or various states' anti-kickback statutes.

Commercial colleagues must not:
- Influence the decision-making process as it relates to publications planning
- Make decisions regarding the prioritization of publications
- Select authors, journals, or the congresses for presentation of publications
- Author a medical or scientific publication
- Comment on draft publications
- Contract with a vendor for a publication
- Liaise with vendors or authors to discuss publications

Publications are managed by Medical, Clinical and Regulatory colleagues to ensure that patient study results are published. These colleagues may also identify gaps in medical knowledge about the product and determine whether existing science can address those gaps through an Iroko-supported publication.

Iroko has adopted the authorship criteria established by the International Committee of Medical Journal Editors (ICMJE) and PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results.

In addition to the ICMJE criteria, authors of an Iroko-supported publication must fully comply with all applicable disclosure obligations. Authors must acknowledge in the publication the individuals who provided editorial support, the funding source, and the author's relationship with Iroko. All external authors of Iroko publications must enter into written agreements describing the scope of work to be performed and the compliance obligations of the authors, including representations that they will adhere to authorship criteria and disclosure obligations.

13. Grants

Commercial colleagues must not participate in any part of the grants process.
After Iroko has made a decision regarding a particular request, a designated member of the Grant Review Committee shall provide a formal written notice of the determination to the requestor.

Iroko considers grant requests from a broad range of nonprofit, health-related organizations. Grant applications must be directed to Iroko's Chief Medical Officer. If a colleague is approached regarding a grant question and/or request, the colleague should inform the requestor that grant requests or inquiries must be sent directly to Iroko's Chief Medical Officer.

The Medical Affairs department manages the grant application process, with oversight from the Grant Review Committee. Iroko provides grants to support healthcare education, charitable, and general philanthropic initiatives, including independent medical education programs, scientific conferences, development of health education materials, patient education programs, and healthcare-related and disease-awareness community activities. Grants may be awarded to hospitals, universities, charitable or social welfare organizations, and other institutions.

Grants must not be provided, directly or indirectly, as an inducement or reward for purchasing, prescribing, recommending, or providing other support for Iroko products. A grant also imposes no obligation, express or implied, on the recipient to purchase, prescribe, provide favorable formulary status for, or otherwise support Iroko products.

Grant recipients must control the content of their programs and activities. Iroko colleagues must not participate in planning or executing any Iroko-funded events, including selecting speakers, suggesting specific topics or attendees, or otherwise scripting content of the sponsored activity or material. Colleagues may not conduct return-on-investment (ROI) or similar analyses of grants; nor may they analyze the impact of grants on HCPs' prescribing practices in connection with any Iroko-supported program.

14. Managed Care Organizations and Government Healthcare Programs

Pharmaceutical manufacturers have become increasingly involved with government customers and stakeholders. For example, many federal and state healthcare programs, including Medicare and Medicaid, purchase or reimburse for the purchase of Iroko medicines. Pharmaceutical manufacturers additionally provide preferred prescription drug pricing to federal customers generally via the Federal Supply Schedule and to specific federal purchasers, including the Department of Veterans Affairs and the Department of Defense. Companies also provide discounts under the Public Health Services 340B Outpatient Drug Discount Program.

Paying or providing benefits to healthcare providers or beneficiaries to prescribe or utilize products ultimately reimbursed by federal healthcare programs potentially implicates the federal Anti-Kickback Statute and state laws. Similarly, failure to provide the government with preferential pricing in certain situations may expose a manufacturer to liability under various federal and state laws. It is critical that Iroko remain vigilant of – and responsive to – all relevant federal and state laws that may be implicated while doing business with the government.

Government employees are subject to strict and complex conflict of interest rules. Because of this, with the exception of those limited interactions by Iroko's Account Managers and other personnel in the Managed Care Department which have already been previously approved, all other sales, marketing and promotional interactions with federal government employees require advance approval by the Compliance Department. "Federal government employees" include physicians, pharmacists, other healthcare practitioners as well as purchasing personnel employed by the Department of Veterans Affairs (VA), Department of Defense (including uniformed military personnel), Indian Health Service, National Institutes of Health, and the Public Health Service.

15. Raising Compliance Concerns

Iroko will not tolerate retaliation against any employee who raises a business practices or compliance issue. Any employee who raises such an issue will be protected from retaliation. This protection extends to anyone giving information in relation to an investigation. However, Iroko reserves the right to discipline anyone who knowingly makes a false accusation, provides false information to Iroko or has acted improperly.

Compliance Helpline Number:
(U.S., Puerto Rico, and Canada)
1-855-IROKO20 (1-855-476-5620)

For colleagues outside the U.S., Puerto Rico, and Canada, dial the following Universal International *Freephone Number:*
+800-1777-9999 or dial +1-720-514-4400
for collect call/reverse charges. If using the collect call number, operator assistance may be required and local charges may apply.

Open Door Policy

Iroko has an "Open Door Policy" and encourages colleagues to discuss all issues, concerns, problems and suggestions with their immediate supervisors or other managers without fear of retaliation.

Compliance Helpline

Where available and permitted by law, Iroko's Compliance Helpline allows colleagues to report a concern or to get information or advice anonymously.

Compliance Helpline

Web-Reporting Tool
Visit www.IrokoComplianceHelp.com to make an online report. Your confidential and anonymous report will instantly and discreetly be forwarded to appropriate personnel in the Compliance Office.

You may also email Compliance@iroko.com

Iroko has a Compliance Officer and an Executive Compliance Committee to help implement and monitor Iroko's compliance program. Every employee plays a role in compliance, however. You are responsible to become familiar with and abide by Iroko's policies and procedures, and requirements communicated to you through departmental guidelines, training programs, and standard operating procedures. All Iroko colleagues who may, as a part of their role, interact with HCPs will receive compliance training, which addresses Iroko policies and procedures, upon hire and on at least an annual basis.

Our compliance program supports prompt response and corrective action as appropriate under the circumstances. All colleagues are critical to maintaining an effective compliance system. You are responsible for raising concerns about risks to the Company — ideally, before these risks become actual problems. If you reasonably believe that there has been a violation of a local, state, or federal U.S. law, law of a foreign country, or specific Iroko policy or procedure, you must report that information immediately to your supervisor, to the Compliance Office, or the Legal Department. Whenever you are in doubt, it is best to raise your concern. By raising concerns, you allow management the opportunity to address potential problems.

It is expected that all referred compliance concerns will be carefully reviewed, thoroughly and thoughtfully investigated in a timely manner, and appropriately resolved. Upon conclusion of an internal investigation, corrective action and preventative measures are determined and implemented as appropriate. In addition, Iroko monitors and periodically audits applicable processes and personnel for compliance with policies and procedures, as well as relevant laws, regulations, and industry guidelines. Iroko may also conduct "for cause" audits and reviews, as needed, as part of its investigation procedures. All Iroko personnel must cooperate with any investigation of a known or suspected violation and answer all inquiries truthfully. Any Iroko employee who withholds information or attempts to mislead or misdirect an investigation is subject to disciplinary action, up to and including termination.

IROKO PHARMACEUTICALS, LLC

IROKO PHARMACEUTICALS, LLC

GLOBAL CORPORATE POLICY		Policy Number: 103A
Title: **Policy on Interacting with Healthcare Professionals – Quick Reference Guide**		Issued: June 20, 2013 Updated: November 15, 2016 Supersedes: Updated version from October 30, 2015 Effective on or before: June 20, 2013
Prepared by: Yvette Warren Title: VP Compliance Date: 11/15/16	Approved by: Moji James Title: SVP and General Counsel Date: 11/15/16	Approved by: Olaolu Imasogie Title: SVP Pharmacovigilance & Med Affairs Date: 11/15/16
	Approved by: Paul Kirsch Title: VP Regulatory Affairs Date:11/15/16	Approved by: Rich Dudek Title: SVP of Marketing and Managed Markets Date: 11/15/16

One Kew Place • 150 Rouse Boulevard • Philadelphia, PA 19112 USA • www.iroko.com • p +1.267.546.3003 • f +1.267.546.3004