Global Policy on Interactions with Healthcare Stakeholders

Version 6.0
11 March 2024

ICONplc.com

Contents

Purpose 3

Scope 3

Definitions 3

References 3

Policy 4

1. Policy Overview 4

2. Anti-Bribary Anti-Corruption Principles 4

2.1 Gifts, Entertainment and Hospitality 5

2.2 Corporate sponsorship and donations 5

2.3 Support for scientific meetings and conferences 5

2.4 Accurately recorded and transparent interactions 5

2.5 Transparency reporting 5

3. Selection of investigators 6

4. Contracts for services 6

5. Maintaining the highest research standards 7

5.1 Patient safety and compliance 7

5.2 Objectivity 7

5.3 Reporting deviations 7

6. Interactions with Regulatory Authorities 7

7. Interactions with Patient Organisations 8

8. Reporting potential misconduct/non-retaliation 8

9. Breach of this policy 8

10. Responsibilities and implementation 8

Document History 9

Purpose

ICON is committed to collaborating with Healthcare Professionals and other Healthcare Stakeholders in a manner that does not have, or appear to have, any undue influence on medical judgment or clinical decision making. This policy establishes the governing principles and expectations to ensure that ICON's relationships with Healthcare Professionals and other Healthcare Stakeholders comply with all applicable laws and regulations.

Scope

This policy applies to all officers, directors (including a non-executive when carrying out his or her duties as a director of ICON plc), and employees of ICON plc, its subsidiaries and branches. We also expect our business partners to live up to these high standards, and it is up to all of us to communicate our expectations regarding these policies clearly.

Definitions

Entertainment:

Meals, beverages and other activities (e.g., sporting, theatre, music or recreational events) involving a Third Party that is not directly related to a business meeting or event

Gift:

Anything of value given to, or received from, a Third Party in connection with ICON's business. A Gift may be any item, tangible or intangible (e.g., job opportunity), that is exchanged with a Third Party, at no cost to the recipient or at a cost which is less than its commercial value.

GCP: Good Clinical Practice.

Government Official:

Any officer or employee of a government, including legislative, administrative and judicial positions, a public international organization, a regulatory agency or any department or agency thereof. This includes doctors, nurses, pharmacists, and hospital or medical administrators working for a wholly or partially government-owned hospital or clinic or other government owned or state run entity. Even those who work for a government agency or entity for a portion of their time are considered a Government Official. It also includes any political official, political party representative or any candidate for political office.

Healthcare Stakeholders:

Healthcare Stakeholders include HCPs, HCOs, members of the scientific community, payors, purchasers, medical professional societies and trade associations, Patient Organizations and patient advocacy groups. This definition includes Healthcare Stakeholders who are officers or employees of a government entity (such as a government-owned hospital, university or research centre) or any other Government Officials.

Health Care Professionals ("HCPs"):

Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his/her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product.

Healthcare Organisation ("HCO"):

Any legal person/entity (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, and other care organization, foundation, university or other teaching institution or medical society and other clinical research organization or (ii) through which one or more HCPs provide services.

Hospitality:

Meals, travel, accommodation and other related, incidental expenses, provided in connection with business activities. Hospitality does not include Entertainment.

KOLs: Key Opinion Leaders.

Patient Organisation ("PO"):

Any non-for-profit legal person/entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers.

HCC Requirements:

Applicable international and local laws, regulations, and industry codes, such as the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals and the European Federation of Pharmaceutical Industries and Associations (EFPIA) codes of practice.

Regulatory Agency:

This refers to any government agency responsible for regulating clinical research, medicines and the pharmaceutical and medical device industry.

SOPs: Standard Operating Procedures.

Third Party (Third Parties):
A person or organization that is not ICON or an employee of ICON with whom ICON interacts, such as HCPs, HCOs, investigators, clients and suppliers.

References
Global Policy on Interactions with Healthcare Stakeholders

- Global Code of Ethical Conduct
- Global Anti-Corruption Compliance Policy
- Global Supplier Code of Conduct
- Global Gifts, Entertainment and Hospitality Policy
- Global Corporate Sponsorship and Donations Policy
- Speak Up Policy
- Site Due Diligence SOP
- Supplier Management for Small or Independent Suppliers SOP
- Key Opinion Leader Contracting Process SOP
- CAPA Procedure SOP
- The Detection and Handling of Suspected Scientific Misconduct SOP
- Management of Serious Breaches of Regulations or Clinical Trial Protocol SOP

Policy

1. Policy overview

At ICON, we are committed to acting with integrity in all we do, including in our interactions with all Healthcare Stakeholders. ICON engages and interacts with HCPs and other Healthcare Stakeholders in many aspects of our business. We must ensure these interactions have no intent or appearance of undue or improper influence on medical judgment or clinical decision making. Healthcare Stakeholders must be engaged based on their education, expertise, knowledge, experience within particular therapeutic area and their direct relationships to the purposes of the engagement. If you discover or suspect any deviations from established standards, legal and regulatory requirements, then it must be promptly reported and appropriately responded to in accordance with this policy.

We each have a responsibility to ensure that any interaction with Healthcare Stakeholders is in accordance with this policy and, when applicable, fully complies with Sponsor guidance and/or approval because they are subject to strict legislation and industry codes.

2. Anti-bribery anti-corruption principles

ICON prohibits any type of corruption, including bribery, facilitation or “grease” payments, or the offering of any improper payments or benefits, regardless of local customs or rationales for the payments or benefits. Everyone at ICON, including Third Parties acting on ICON’s behalf, must never directly or indirectly give anything of value to any Third Party with the intention to improperly obtain or retain business or gain any business advantage, or to improperly influence the recipient’s behaviour. All transactions must be reasonable, justified, and fully transparent.

See the Global Anti-Corruption Compliance Policy for further guidance.

In some countries, HCPs and site staff are employed by or affiliated with the government or regulatory authorities, either directly or through state-owned healthcare facilities, so they may be defined as Government Officials and covered by applicable anti-bribery laws. Interactions with Government Officials anywhere in the world must comply with applicable laws, rules, and regulations, including but not limited to the US Foreign Corrupt Practices Act (FCPA), French ‘Sapin II’ law and the UK Bribery Act (UKBA).

Any benefits provided to or on behalf of any Government Official and/or other Third Parties must comply with ICON’s policies including but not limited to the pre-approval and value limits established in the Global Anti-Corruption Compliance Policy and/or Global Gifts, Entertainment, and Hospitality Policy.

2.1 Gifts, Entertainment and Hospitality

We must all ensure any Gift, Entertainment and/or Hospitality provided to Healthcare Stakeholders will comply with our Global Gifts, Entertainment and Hospitality Policy. Strict requirements apply when interacting with Healthcare Stakeholders, including spending limits and pre-approval requirements. In many circumstances and locations, providing Gifts and Entertainment to Healthcare Stakeholders is not permitted.

Consult the Global Gifts, Entertainment and Hospitality Policy for further guidance.

2.2 Corporate sponsorship and donations

Donations and corporate sponsorships to healthcare related events and activities must be tied to ICON's mission and align with our core values.

We must ensure that any corporate donation or sponsorship is not provided with the intention to improperly obtain or retain business or gain any business advantage, or to improperly influence the recipient's behaviour.

Please consult the Global Corporate Sponsorship and Donation Policy for guidance and requirements regarding the provision of corporate sponsorships and donations to Healthcare Stakeholders.

2.3. Support for scientific meetings and conferences

ICON may fund scientific meetings and conferences on behalf of ICON or its sponsors. The main purpose of funding medical and scientific congresses, conferences, symposia and similar programs must be scientific exchange or medical exchange. Consult ICON's Global Corporate Sponsorship and Donation Policy for further guidance.

ICON may also organize investigator meetings on behalf of sponsors. The Investigator Meeting Team must be consulted in advance and all applicable ICON and sponsor requirements and SOPs adhered to when organising and coordinating investigator meetings.

2.4 Accurately recorded and transparent interactions

ICON's books and records must accurately reflect all financial transactions and the use of the company's assets, which means that transactions and uses of assets are recorded in reasonable detail, and in accordance with ICON's Global Anti-Corruption Compliance Policy.

To avoid any perception of bribery or undue influence, various restrictions apply to the amount, purpose and form of compensation which may be offered to Healthcare Stakeholders. HCOs, HCP's or their employees must not be offered or paid compensation or any other benefit:

– That is tied to the outcome of a study or project;

– That includes payments outside the study or services for which they were engaged;

– For referring potential study participants other than the costs incurred in administration or any costs reasonably incurred for necessary assessment;

– That includes special incentives such as enrolment bonuses, awards, or gift certificates designed to reward the achievement of participant enrolment goals within a specified time period; or

– That includes any other type of additional incentive or reward, except those identified in a written agreement with recipient (e.g. Clinical Trial Agreement) and approved by the sponsor and where relevant, the competent Institutional Review Board or Ethics Committee.

Any exceptions to the above must be permitted by law, not violate any anti-bribery or anti-corruption requirements and be approved by the sponsor and the Ethics and Compliance Team.

2.5 Transparency reporting

ICON's interactions with Healthcare Professionals, Healthcare Organizations and Patient Organizations must comply with all applicable transparency reporting requirements for payments and transfers of value to such recipients. If applicable to your role, you must be familiar with applicable transparency reporting requirements, including any local, regional or sponsor requirements, and ensure these are built into applicable ICON processes.

Consult Global Gifts, Entertainment and Hospitality policy and Investigator meeting playbook for further guidance. If you have any questions please contact the Investigator Payments Group at SunshineActReports@iconplc.com and/or the Ethics and Compliance team through the Legal Portal available the in MyICON or directly at ICONlegal.onit.com. If you are interacting with a French based HCP please consult the French Transparency and the French Anti-Gift guidance available on Ethics & Compliance team MyICON page.

3. Selection of investigators

HCPs selected to participate in trials must meet high standards of professional excellence and ethical behaviour. ICON's Site Due Diligence SOP establishes the criteria applied and procedures to be followed to ensure that duly qualified and experienced investigators are selected. The Site Due Diligence SOP establishes the background check criteria and process for sites and investigators. If applicable to your role, you must familiarise yourself and comply with these procedures.

We all have a responsibility to report any investigator conduct that may violate applicable law and/or ICON policies and should follow applicable procedures in order to ensure ICON's information systems are updated with investigator performance-related information. Timely updates will ensure that trial subjects are safeguarded, scientific validity is not compromised and studies managed by ICON meet all relevant regulatory requirements.

4. Contracts for Services

ICON may enter into fee-for-service arrangements with HCPs as consultants to perform bona fide consulting services for which ICON has a legitimate business need. Such arrangements may include research, drug development, participation on advisory boards, presentations at training and other services supporting ICON's business. ICON must always select HCPs based upon their education, expertise, knowledge, experience within particular therapeutic area and their direct relationships to the purposes of the consulting arrangements. Meetings must take place in a venue conducive to the effective exchange of scientific information and must comply with our Global Gifts, Entertainment and Hospitality Policy.

We must not enter into consulting arrangements with HCPs in order to influence or encourage recipients to influence the outcome of clinical trials, or to reward HCPs for any such past behaviour. Service arrangements with HCPs must be documented in formal written and signed agreements that specify the services to be performed and the compensation to be provided. Appropriate Procurement procedures must be followed, including the Supplier Management for Small or Independent Suppliers SOP and Key Opinion Leader Contracting Process SOP.

Compensation paid to an HCP must be reasonable and reflect the Fair Market Value of the services being provided and the time spent on services by the HCP (taking into account the HCP's main country of residence/ work and any local ICON Standards). All payments must be adequately supported by documentation, accurately recorded in reasonable detail in ICON's books and records and meet the guidelines provided in **Section 2.4** above.

We all have a responsibility to report any actual or suspected HCP conduct that may violate applicable law and/or ICON policy and follow applicable procedures in order to ensure ICON's information systems are updated with investigator performance-related information. Timely updates will ensure that trial subjects are safeguarded, scientific validity is not compromised and studies managed by ICON meet all relevant regulatory requirements.

If you have any questions or need further information regarding HCP engagements, via the Legal Portal available in MyICON or directly at ICONlegal.onit.com.

5. Maintaining the highest research standards

ICON recognises that the primary duty of HCPs is to their patients and the most important aspect of that duty is patient safety. This principle underpins industry codes and standards and is reflected in all relevant laws and regulations including federal/national or local/state laws.

5.1 Patient safety and compliance

We must always operate to accepted ethical principles for clinical research such as those set forth in the Declaration of Helsinki, the GCP Guidelines of the International Conference of Harmonization, the Nuremburg Code, the Belmont Report and relevant national and local legal and regulatory standards. Our operational policies, procedures and business practices have been developed to promote compliance with these ethical principles, GCP standards and applicable legal and regulatory requirements.

5.2 Objectivity

To ensure objective assessments are provided and to guard against negative perceptions, we must maintain an appropriate professional relationship with site staff. Cordial relationships are valuable and important but over-familiarity may be perceived as a lack of objectivity. Clinical Research Associates in particular should be aware that socializing with site staff could be interpreted as impacting their ability to monitor the site at arm's length. You must be familiar with the principles and limits established in ICON's Global Gifts, Entertainment and Hospitality Policy when interacting with site staff and other Healthcare Stakeholders.

5.3 Reporting deviations

We all have a responsibility to report any suspected significant deviations related to the conduct of a trial such as (i) deviations that might adversely impact patient safety or subject rights; (ii) serious non-compliance with accepted ethical research norms; (iii) deviations which may impact the integrity of the study data; (iv) repeated departures from the study protocol; or (v) the falsification of research records, using the designated reporting channels as set out in the following:

- Nonconformance Identification and Management SOP;
- The Reporting and Handling of Suspected Scientific Misconduct SOP; and
- Management of Serious Breaches of Regulations or Clinical Trial Protocol SOP

If you are unsure about the best way to raise your concern, consult your People Leader or refer to the Speak Up Policy for further guidance.

6. Interactions with regulatory agencies

ICON may work closely with Regulatory Agencies involved in decision making and standard setting with respect to clinical research and drug development. Such interactions must be professional, relate to a legitimate business need and be done with the approval and awareness of our sponsors. Our interactions must be collaborative only, with a shared mission to support clinical development. ICON must not engage these stakeholders in any paid relationship and any exception to this must be approved in advance by the sponsor and relate to a legitimate and appropriate business need.

7. Interactions with Patient Organisations

ICON may, from time to time, work with Patient Organizations on behalf of sponsors e.g. to perform market research, consultancy or disease awareness campaigns. In working with Patient Organizations, we must always respect their independence and ensure that our interactions are fully compliant with all ICON and sponsor polices and instructions and any applicable HCC Requirements and/or industry codes.

Any information we provide to Patient Organizations must be accurate, balanced, fair, objective and substantiated.

ICON may also act with Patient Organisations as part of ICON community activities e.g. via the provision of donations or sponsorship. Consult ICON's Global Corporate Sponsorship and Donation Policy for further guidance.

8. Reporting potential misconduct/ non-retaliation

ICON has an open door policy that encourages raising concerns and reporting violations or potential violations of this Policy. Even if you only suspect that a violation has occurred or has the potential to occur, you should Speak Up. People Leaders are responsible for supporting compliance with this and other policies by maintaining an open door for their team members and others who may reach out to them.

If you do not feel comfortable speaking up to your People Leader, or if is not practical under the circumstances, or you have reported to your People Leader but do not feel the issue has been adequately addressed, you may choose to make a report through appropriate internal channels outlined in the Speak Up Policy.

Reports may also be made via ICON's Speak Up global helpline, Ethics Line. Ethics Line is administered by an independent company, is available 24 hours a day, 7 days a week, and can accommodate calls in more than 75 languages. Reports may be made online, by phone or by mobile.

Ethics Line

Ethics Line can be accessed via the MyICON homepage, directly at ICON.ethicspoint.com or via QR Code.

In all instances where a concern is raised on a confidential or anonymous basis, every effort will be made to ensure that information relating to a reported violation is kept confidential and communicated on a need-to-know basis only.

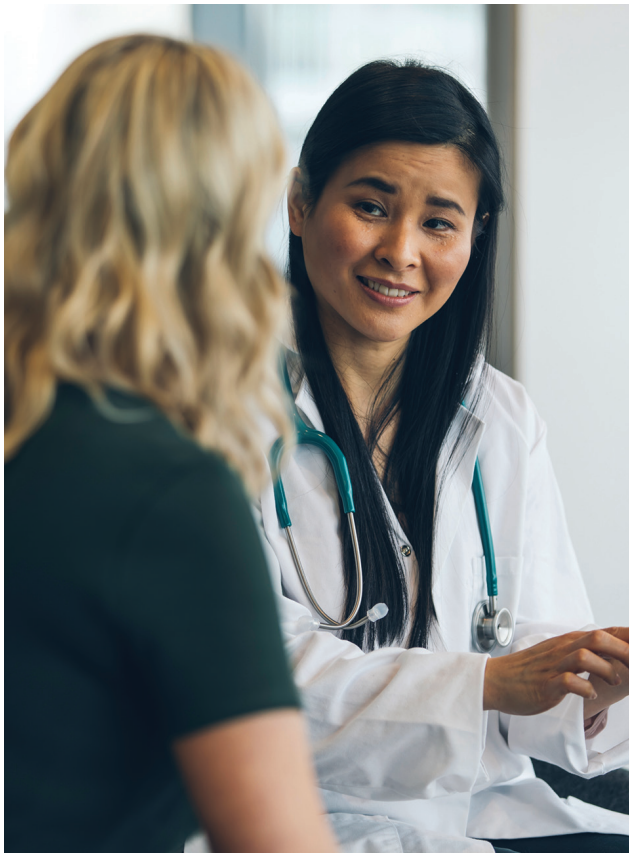
ICON's Speak Up Policy prohibits retaliation against anyone who in good faith reports an actual or suspected violation of this policy.

9. Breach of this policy

Conduct by an employee that violates this policy is contrary to ICON's terms and conditions of employment. If, following an investigation, a breach is found to have occurred, the breach may be grounds for disciplinary action up to and including termination of employment consistent with applicable law.

10. Responsibilities and implementation

We are all individually responsible for ensuring we adhere to the principles and rules set out in this policy. People Leaders are also responsible for promoting compliance with this policy within their area of functional responsibility, to lead by example, and to provide guidance to their teams.



Document history

Effective date	Version	Brief summary of changes
11 Nov 2013	v.1	Document created
15 July 2015	v.2	Procedure modified to include: – Scope updated in line with new format style – Reference updated with new replacement numbers (DCRF 15274 closed)
19 Dec 2016	v.3	Policy updated in line with new policy format style. No substantive updates.
22 Apr 2022	v.4	Policy format updated and content changes to include: - Anti-bribery and anti-corruption principles - Accurate books and records - Scientific meetings and conferences - Interactions with Regulatory Agencies - Interactions with Patient Organisations - Financial disclosure
14 Sept 2022	v.5	Minor typographical error correction.
11 March 2024	v.6	Update to align definitions and cross references across policies sponsored by Legal Ethics and Compliance Program and further Speak Up information

ICON plc Corporate Headquarters
South County Business Park
Leopardstown, Dublin 18
Ireland
T: (IRL) +353 1 291 2000
T: (US) +1 215 616 3000
F: +353 1 247 6260

ICONplc.com/contact