Global Policy on Interactions with Healthcare Stakeholders

Our Mission:
To help our clients to accelerate the development of drugs and devices that save lives and improve quality of life.

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ICONplc.com

Contents

Purpose

ICON is dedicated to the advancement of clinical research and the development of healthcare products that will improve patient care. We are 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.

To ensure our commitment to the highest standards of ethics and integrity, ICON has adopted this Global Code on Interactions with Healthcare Stakeholders which outlines the governing principles and basis of our interactions with Healthcare Stakeholders around the world.

ICON's relationships with Healthcare Professionals and other Healthcare Stakeholders shall comply with all applicable laws and regulations. Where local laws, regulations, industry codes of practice and policies set higher standards, they must take precedence over the Global Code.

Further information may be found on the topics addressed in other resources available to ICON employees such as ICH, GCP, ICON Standard Operating Procedures (SOPs), Working Procedures (WPs) and training modules.

Scope

This Policy applies globally to all employees, officers, directors, contractors, and agents of ICON plc and its subsidiaries and branches ("ICON").

Definitions

GCP: Good Clinical Practice.

Government Official ("GOs"): For the purposes of this document, Government Official includes any officer or employee of a foreign 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, healthcare funds 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 foreign political official or any candidate for political office.

Healthcare Stakeholders: Defined as the following: Healthcare Professionals, Healthcare Organizations, Members of the Scientific Community, Payors, Purchasers, Professional Societies and Trade Associations, Patient Organizations and Patient Advocacy Groups. This definition includes members of the Healthcare Community who are officers or employees of a Government Entity (such as a hospital, university or research center) or any other Government Officials.

Health Care Professionals ("HCPs"): HCPs include those individuals and entities who may or do administer, purchase, lease, recommend, use, pay for, reimburse, authorize, approve, supply, arrange for the purchase or lease of or prescribe medical device products, including any members of the medical, dental, pharmacy or nursing professions, and relevant associated administrative staff; and/or hospitals and other care organizations, health plans, health insurers, managed care organizations, pharmacies, formulary or benefit administrators and other clinical research organizations, and relevant staff at such entities.

Health Care Organizations ("HCOs"): For the purposes of this Policy, any of the following entities are considered "Health Care Organizations": any entity who may or do administer, purchase, lease, recommend, use, pay for, reimburse, supply, arrange for the purchase or lease of or prescribe medicinal or medical device products, including any members of the medical, dental, pharmacy or nursing professions; and/or hospitals and other care organizations, health plans, health insurers, managed care organization, pharmacies, formulary or benefit administrators and other clinical research organizations.

Definitions cont'd

ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

KOLs: Key Opinion Leaders.

Patient Organizations: This typically refers to a not for profit organization that primarily represents the interests and needs of patients, their families and/or caregivers.

PhRMA Code: The Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals.

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

SOPs: Standard Operating Procedures.

Third Party (Third Parties): Third Party(ies) refers to any person or organization who is not ICON or an employee of ICON, with whom ICON employees interact, such as members of the Healthcare Community, Investigators, Sponsors, suppliers, vendors or Sub-Contractors.

References

EX002-POL: Global Code of Ethical Conduct

LEG001-POL: Anti-Corruption Compliance Policy

LEG013-POL: Global Gifts and Hospitality Policy

LEG014-POL: Sponsorship and Donations Policy

SST002-SOP: Site Due Diligence

ICON Supplier Code of Conduct

1. Working with Healthcare Stakeholders on Clinical Studies

One of the most common interactions between ICON employees and Healthcare Stakeholders is our work with investigators, site staff, nurses, pharmacists and other healthcare workers during the lifetime of a clinical trial. For instance, ICON may engage Investigators or Sites on behalf of Sponsors in the running of clinical trials, engage consultants or KOL's to advise on aspects of drug development, manage sites and investigators in the context of ICON's Accellacare Network or engage with nurses through the Symphony network.

1.1 Anti-Bribery Anti-Corruption Principles

ICON's Global Anti-Corruption Policy prohibits corruption or bribery of individuals and entities, including foreign Government Officials, HCPs, and commercial organizations. ICON does not tolerate 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. ICON personnel or third parties acting on ICON's behalf may never directly or indirectly give anything of value with the intention to improperly obtain or retain business or gain any business advantage, or to improperly influence the recipient's behavior.

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. Additional laws, policies or procedures may apply to situations where you are dealing with a HCP or site staff who are Government Officials.

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) 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. In addition, any transactions with such entities or individuals must be reasonable, justified, and fully transparent.

Further information on the restrictions that apply are available in ICON's Anti-Corruption Compliance Policy (LEG001-POL) and Global Gifts and Hospitality Policy (LEG013-POL).

1.2 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 must be in accordance with ICON's Anti-Corruption Compliance Policy (LEG001-POL).

All payments must be adequately supported by documentation and accurately recorded in reasonable detail in ICON's books and records.

In order to ensure transparency and avoid any perception of bribery or undue influence, various restrictions apply to the amount and form of compensation which may be offered to Healthcare Stakeholders. As part of this, HCOs, HCP's or their employees may 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 enrollment bonuses, awards, or gift certificates designed to reward the achievement of participant enrollment 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 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.

1.3 Selection of Investigators

Healthcare Professionals selected to participate in trials which ICON is running must meet high standards of professional excellence and ethical behavior. SST002-SOP sets out the procedures to be followed in relation to selection of Investigators on a clinical trial. Sponsors may also have their own specific selection requirements which must also be followed. These are designed to ensure that duly qualified and experienced investigators are selected. The required background checks are also set out in full in the relevant SOP. Relevant officers and employees must be familiar with these procedures and they must be adhered to in full.

ICON's proprietary iSPRINT database has been designed to record information on performance of Investigators and other site staff. It is important that staff follow the applicable procedures in order to ensure

2. Contracts for Services

ICON may enter into fee-for-service arrangements with Healthcare Professionals 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, and presentations at training. ICON must always select Healthcare Professionals based upon their education, expertise, knowledge, experience within particular therapeutic area and their direct relationships to the purposes of the consulting arrangements. Consultant meetings must take place in a venue conducive to the effective exchange of information and must be designed to ensure active participation for attendees.

ICON may not enter into consulting arrangements with Healthcare Professionals in order to influence or encourage recipients to influence the outcome of clinical trials, or to reward Healthcare Professionals for any such past behavior. Consultant arrangements must have written and signed consultant agreements that specify the services to be performed and the compensation to be provided. Appropriate templates can be obtained from the legal or legal compliance team. Compensation for consulting services must be reasonable and reflect the Fair Market Value of the services being provided and the time spent on services by the consultant.

All fees paid to a consultant must not exceed the fair market value of what is appropriate and reasonable in value (taking into account the consultant's main country of residence / work and any local ICON Standards).

ICON's information systems are updated as necessary with details of performance to ensure that trial subjects are safeguarded, that scientific validity is not compromised and that all relevant regulatory requirements are complied with.

If you have any questions or seek further information in relation to the above, you should contact the Study Start-Up Unit.

3. Maintaining High Research Standards

ICON recognizes that the primary duty of Healthcare Professionals 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.

Patient Safety and Compliance

ICON must always operate to accepted ethical principles for clinical research such as those set forth in the Declaration of Helsinki, the Good Clinical Practice Guidelines of the International Conference of Harmonization, the Nuremburg Code, the Belmont Report and relevant national and local standards. Furthermore, ICON staff must ensure that, as far as is practical, the scientific validity of all operations is preserved.

Our operational policies, procedures and business practices help us to meet these ethical principles, Good Practice standards and legal requirements. All employees must follow these policies and procedures.

Staff Objectivity

In order to ensure objective assessments are provided and to guard against negative perceptions, ICON staff must maintain an appropriate professional relationship with site staff. Cordial relationships can work well during the course of a study but over-familiarity could lead to a perception of 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. Employees are obliged to be familiar with the principles and limits contained in ICON's Global Gifts and Hospitality Policy when interacting with site staff and other Healthcare Stakeholders.

Reporting of Deviations

Obligations related to the reporting of protocol deviations and non-compliance with regulations and SOPs also impact on the day-to-day interactions of ICON staff working with Healthcare Stakeholders. 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 must be reported via the various escalation pathways in ICON as follows:

- Your Line Manager
- Clinical Study Manager
- Quality and Compliance
- Legal Business Partner
- Legal Compliance
- Ethics Line (a confidential reporting line).

Appropriate remedial action must be promptly taken and staff must seek to ensure that future recurrences do not happen.

Summary

The dominant principle informing the legal framework in which ICON operates is that of subject protection and safety. ICON staff must maintain arm's length relationships with site staff so there can be no question of partiality in their monitoring or other interactions.

4. Hospitality

ICON personnel may not offer or provide any gifts, entertainment, or recreational activities to Healthcare Professionals under any circumstances or in any locality. ICON personnel may not offer or provide educational items, business courtesy items or meals to Healthcare Professionals where such items or meals are prohibited by local laws or regulations or by ICON's Global Gifts and Hospitality Policy. Neither may ICON personnel offer or provide business courtesy items or meals in order to improperly influence a decision affecting any of ICON's business. Anything we provide of value must be given without expectation of reciprocity, explicit or implied obligation, favour, or action in return. Business courtesy items and hospitality may require pre-approval. Please consult ICON's Global Gifts and Hospitality Policy (LEG013-POL) for further guidance.

5. Sponsorship and Donations

ICON is committed to giving back to the communities in which we do business. The giving of donations together with the provision of sponsorships to healthcare related events and activities, is central to our efforts and aligns with our core values as a Company.

Because ICON and our clients operate in a highly regulated area, our interactions with external Third Parties are regularly scrutinized, in particular those with members of the Healthcare Community. It is important to ensure that any provision of funding or other benefits-in-kind to such Third Parties are appropriate, compliant with applicable laws and regulations and align with our Company values.

ICON employees should consult ICON's Sponsorship and Donations Policy (LEG014-POL) for detailed guidance and requirements regarding the provision of sponsorships and donations to Healthcare Stakeholders.

6. Support for Scientific Meetings and Conferences

ICON may fund scientific meetings and conferences on behalf of ICON or their sponsors. The main purpose of funding medical and scientific congresses, conferences, symposia and similar programs must be scientific exchange or medical exchange. 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 must be adhered to when organizing and coordinating investigator meetings. ICON employees should also consult ICON's Sponsorship and Donations Policy (LEG014-POL) for further guidance.

7. 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 so 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 e.g. need to engage ethics committees.

8. Interactions with Patient Organizations

ICON may, from time to time, work with Patient Organizations on behalf of clients 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. Any information we provide must be accurate, balanced, fair, objective and substantiated.

We may also act with Patient Organizations as part of ICON community activities e.g. via the provision of grants or sponsorship. ICON employees should consult ICON's Global ICON's Sponsorship and Donations Policy (LEG014-POL) for further guidance.

9. Financial Disclosure

ICON's interactions with Healthcare Professionals, Healthcare Organizations and Patient Organizations will comply with all applicable transparency reporting requirements for payments and transfers of value to such recipients. ICON employees must be familiar with any local or regional transparency requirements and ensure these are built into ICON processes. In addition, such requirements may also come from sponsor directions, to which ICON must also adhere. If you have any questions please contact the Investigator Payments Group or Legal Compliance for further information.

10. Further Information

If you have any questions or want to seek further information in relation to this Policy, you should contact your line manager, study manager or a representative from Quality and Compliance or Legal Compliance.

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