ICON
A Symbol of Excellence

Global Policy on Interactions with Healthcare Professionals

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

Contents

Purpose

Because ICON operates in a highly regulated area, this Policy is designed as an aide in understanding some of the main requirements which apply to our interactions with external healthcare professionals and it highlights where further information may be obtained.

Scope

This procedure applies to all staff in ICON plc.

Definitions

PhRMA Code:	The Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals.
PVM:	Procurement and Vendor Management.
VCAR:	Vendor Correction Action Request applied to Preferred PVM Vendors.
VCAR System:	A database developed for establishing a VCAR electronically to support tracking and communications plus formally closing the VCAR when complete.

References

CO004-SOP:	Reader Contracting Process
LEG001-POL:	Anti-Corruption Compliance Policy
LEG006-SOP:	Development of Regional Master and Country Level Clinical Trial and Clinical Study Agreements
PRO001-SOP:	Global Supplier List – Onboarding and Management
QA001-WP013:	Central Labs (CL) Supplier Quality Assessment
SST002-SOP:	Site Selection

POLICY

Working with Healthcare Professionals

– ICON works with external healthcare professionals (HCPs) or General Practitioner (GP) across many parts of its business. This involves regular interactions with physicians, nurses, pharmacists and others across all aspects of clinical trials. Such interactions with healthcare professionals often occur when ICON is working on behalf of our Sponsors - for example, when ICON engages Principal Investigators on behalf of Sponsors in the running of clinical trials, uses HCPs to advise on aspects of drug development or contacting HCPs/GPs for a letter on the prospective subject's medical history.

Because ICON operates in a highly regulated area, this Policy is designated as an aid in understanding some of the main requirements which apply to our interactions with external healthcare professionals and it highlights where further information may be obtained.

PLEASE NOTE THAT SOME ASPECTS OF THIS POLICY AND REFERENCED SOPs MAY NOT APPLY TO ALL DIVISIONS.

Contents of the Policy

– The activities of ICON's employees when working with HCPs fall under the remit of many laws, regulations, codes of practice and ethical conventions. This Policy is aimed at providing guidance to ICON staff in relation to working with healthcare professionals in the following areas: (i) Research Standards; (ii) Financial Ethics; (iii) Selection of Investigators; (iv) Feedback and Assessment; (v) Government Officials; (vi) Research/Educational Grants and Contributions to Charities; and (vii) Disclosure of Clinical Trial Information/Results.

Purpose of the Policy

– The purpose of this Policy is to ensure that all ICON interactions with HCPs are appropriate and are seen to be appropriate. The Policy ensures that interactions are professional exchanges designed to be of ultimate benefit to patients and the practice of medicine. This Policy is designed to be a reference document setting out some key principles and indicating where further information may be found on the topics addressed as many of the areas covered in this Policy are addressed in other resources available to ICON staff such as ICH, GCP, ICON Standard Operating Procedures (SOPs), Working Procedures (WPs), training modules, clinical reference materials, the ICON Global Code of Conduct and so on.

What if Legal Provisions Conflict?

– ICON is committed to compliance with applicable legal, regulatory and professional requirements in all countries in which it operates. In all cases, compliance with local laws is required. In some instances, a conflict may arise between the contents of this Policy, applicable laws and regulations, professional requirements or industry standards. Should this occur, it is ICON's policy that the more restrictive provision shall apply.

1. Research Standards

Through all its dealings with healthcare professionals, 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 whether federal/national or local/state laws.

1.1 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. Furthermore, ICON staff must ensure that, as far as is practical, the scientific validity of all operations is preserved. ICON staff must conform with all regulations including the Good Clinical Practice Guidelines of the International Conference of Harmonization, the Nuremburg Code, the Belmont Report and relevant national and local standards and adherence to ICON Standard Operating Procedures (SOPs) and Working Procedures (WPs) is the means by which this is obtained. Our policies, procedures and business practices help us to meet ethical principles, Good Practice standards and legal requirements. Staff must follow these policies and procedures.

1.2 Protection of Patient Privacy

Data privacy laws and regulations such as the US Health Insurance Portability and Accountability Act 1996 (HIPAA) and the EU Data Protection Directive require Investigators to protect the confidentiality of any health information about a study participant. Investigators are obligated to obtain informed consent from the participant before the information is disclosed to the Sponsor or a CRO. Detailed information about the obligations on ICON staff to protect the confidentiality of information relating to study participants is covered in ICON's Binding Corporate Code of Conduct on Data Protection which is available in the EDMS system.

1.3 PhRMA and Equivalent Codes

The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals (PhRMA Code) was developed and adopted by many leading research-based pharmaceutical and biotechnology companies. These companies publicly certify each year that they are in compliance with the terms of the Code. The PhRMA Code is intended to protect patients from undue influences on decision-making by

HCPs. For example, the PhRMA Code prohibits the use of "token" consulting arrangements which might include payments to Investigators to encourage or reward the use of a particular brand, rather than as a genuine payment for participation on a trial. Relevant ICON staff should be familiar with the terms of the PhRMA Code and further information on the PhRMA Code is posted on the Legal homepage of MyICON. Other similar codes may be relevant in other jurisdictions and for other services, for example, the Advanced Medical Technology Association (AdvaMed) Code for the devices industry.

1.4 Study Protocols

All clinical trial protocols must be reviewed and approved by local Institutional Review Boards or Ethics Committees, unless a legal exemption applies. ICON staff members working on those trials must be familiar with and understand the terms of the Study Protocol. Site monitoring in accordance with relevant SOPs is key to ensure that the Study Protocol is being followed and relevant standards are adhered to.

1.5 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 HCPs. Any suspected significant deviations related to the conduct of a trial such as (i) deviations that might impact patient safety or subject rights including privacy; (ii) 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. Appropriate remedial action must be promptly taken and staff must seek to ensure that future recurrences do not happen.

1.6 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. CRAs in particular should be aware that socializing with site staff and so on could be interpreted as impacting the CRA's ability to monitor the site at arm's length.

1.7 Compliance and Training services to our clients?

Relevant ICON staff are obliged to be familiar with the rules and regulations which relate to the running of trials and therefore impact on ICON's dealings with Healthcare Professionals. Staff training is provided to ensure relevant staff are familiar with the regulations which apply to their activities and all staff are required to complete their specific training schedules in due time in order to ensure they are adequately briefed on regulatory issues.

1.8 Further information

If you have any questions or seek further information in relation to the above, you should contact your line manager or a representative from the Quality Assurance Department.

Summary

The dominant principle informing the legal framework in which ICON operates is that of subject protection including safety, privacy and the preservation of all other rights. Completion of assigned training modules is an essential element in ensuring that ICON staff are equipped to perform their work in a legally compliant manner. 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.

2. Financial Ethics

2.1 Contracts for Services

ICON may hire qualified healthcare professionals as researchers to provide advice, expertise and/or additional resources. Such engagements must be permitted by law and serve a clear business purpose. All vendor contracts must contain a clear description of the services to be provided and fees to be paid. The services in question must not interfere, or appear to interfere, with the healthcare professional's independent medical judgment. Interactions with healthcare professionals must comply with ICON's Anti-Corruption Compliance Policy (LEG001-POL).

2.2 Setting Fees

Payments to healthcare professionals must be in line with fair market value for the services involved. In relation to payments for participation in a clinical trial, a selection of studies use a proprietary database called Grantplan to generate Investigator payments. The Study Start-Up Unit within ICON is, at the date of this Policy, reviewing the company's policy as regards utilization of Grantplan. The procedures outlined in PRO001-SOP (Global Supplier List – Onboarding and Management), equivalent CL process QA001-WP013 (Central Labs (CL) Supplier Quality Assessment) and SST002-SOP (Site Selection) and other SOPs including LEG006-SOP (Development of Regional Master and Country Level Clinical Trial and Clinical Study Agreements) must be followed in order to ensure consistency and transparency across the ICON Group.

2.3 Financial Disclosure

ICON supports Sponsors in relation to the disclosure of financial and other interests and relationships that may create apparent or actual conflicts of interest. Forms 1572 or equivalents are used in the US, as well as in other countries.

ICON also recognizes and supports the steps taken within the pharmaceutical industry to embrace greater transparency in relation to payments made by pharmaceutical companies to healthcare professionals, as pharmaceutical companies make increased voluntary public disclosures of payments made to Principal Investigators. All queries related to such disclosures should be directed towards a representative from the Finance Department.

All documentation related to the setting of Principal Investigator fees must be retained on file for at least three (3) years or longer if so required by other regulatory requirements. In relation to payments made to Investigators, the procedures applicable to the Investigator Payment Group and to other finance staff involved in the making of payments to Investigators must be adhered to in full.

2.4 Restrictions on Forms of Compensation

In order to ensure transparency, various restrictions apply to the form of compensation which may be offered to healthcare professionals. As part of this, healthcare institutions, healthcare professionals or their employees may not be offered or paid compensation or any other benefit that:

- is tied to the outcome of a study;
- includes payments to physicians outside the study for referring potential study participants other than the costs incurred in administration or any costs incurred for assessment necessary;
- includes special incentives such as enrollment bonuses, awards, or gift certificates designed to reward the achievement or participant enrollment goals within a specified time period; or
- includes any other type of additional incentive or reward, except those identified in the clinical study agreement with an Investigator Site and approved by the relevant institutional review board or ethics committee.
- Unless approved by a Sponsor and where there is no corrupt intent and if permitted by applicable law.

2.5 Hospitality

As part of its business, ICON organizes meetings and training sessions attended by Principal Investigators. This is carried out on behalf of Sponsors and it is a matter for Sponsors to approve budgets proposed. If an ICON officer or employee has any concerns about inappropriate levels of hospitality, these should be reported to their line manager.

2.6 Standard of Care Services

Sponsors often cover the cost of the investigational aspects of the study such as providing the investigational product and the costs of any treatments, procedures or tests that are required under the protocol. Under some study protocols, certain Standard of Care (SOC) services are required. These are medically necessary treatments, equipment, procedures or tests that would be administered to the patient as part of good medical practice, whether or not that patient was participating in the trial. Sponsors are required to meet local legal requirements in deciding whether or not such costs should be covered as part of the trial costs. ICON staff should report any concerns they may have to their line manager if it appears that the levels of costs covered may raise ethical concerns about the impartiality of the Investigator.

Payments to Investigators under the heading of reimbursement of expenses must be reasonable.

2.7 Further Information

If you have any questions or seek further information in relation to the above, you should contact your line manager or a representative from the Quality Assurance Department.

Summary

Transparency is of key importance in the area of financial dealings with HCPs. This applies in the case of setting fees and agreeing to other forms of compensation. If any concerns arise in relation to inappropriate levels of compensation, these should be reported to your line manager. Further information is available from the Quality Assurance Department.

3. Selection and Ongoing Assessment of Investigators

3.1 Requests from Physicians Interested in Becoming Investigators

HCPs volunteer to participate in clinical research for a variety of reasons. In selecting a HCP to participate in such research, ICON must ensure that the process used will result in research outcomes that are of benefit to patients and enhance the practice of medicine. Not all HCPs who volunteer to participate will be qualified to be clinical investigators and this could be due to insufficient training/ qualifications, inadequate facilities or lack of experience.

3.2 Selection of Principal Investigators

Healthcare professionals selected to participate on 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. 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.

CO004-SOP provides for on-boarding and assessment of IMI independent reviewers, independent readers and similar functions.

3.3 Ongoing Assessment

PRO001-SOP provides the mechanism for ICON staff to provide feedback and assessments of the quality and performance level of "Preferred Suppliers" as defined in PRO001-SOP. (Please note that the VCAR system can be used to report ethical concerns for all vendors.) ICON's proprietary iSPRINT database has been designed to record the information about performance of PIs. It is important that staff follow the applicable procedures in order to ensure 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.

QA001-WP013 provides for on-going assessment of CL suppliers.

3.4 Further information

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

Summary
The dominant principle informing the legal framework in which ICON operates is that of patient safety. Completion of training is an essential element in ensuring that ICON staff are equipped to perform their work in a legally compliant manner. ICON staff also has to maintain arm's length relationships with site staff so there can be no question of partiality in their monitoring.

4. Government Officials

4.1 HCPs who are Government Officials

In some countries, healthcare professionals are employed by or affiliated with the government or regulatory authorities, either directly or through state-owned healthcare facilities. Over and above the restrictions on dealing with healthcare professionals generally as set forth in this Policy, additional laws, policies or procedures may apply to situations where you are dealing with a healthcare professional who is a government official.

"Government officials" is a very broad term and may include healthcare professionals and scientists that work at public institutions, such as government-run hospitals. It may also include people who work even for a portion of their time for such bodies.

When dealing with HCPs who are government officials, it should be noted that some key anti-bribery legislation, such as the U.S. Foreign Corrupt Practices Act and the UK Bribery Act, is particularly targeted at the corruption of such officials. Therefore, extra caution should be exercised when dealing with healthcare professionals who are government employees. Further information on the restrictions that apply is available in ICON's Anti-Corruption Policy (LEG001-POL).

Summary
You should be familiar with the restrictions set out in ICON's Anti-Corruption Policy as regards dealings with HCPs who are employed by or affiliated with government or regulatory authorities.

5. Clinical Trial Information/Results

5.1 Disclosure

ICON acknowledges the sensitivities which surround the disclosure of clinical trial results. The data from a clinical trial is the property of the relevant Sponsor and ICON and its employees must ensure that they do not breach the policy applied by the Sponsor relating to disclosure. This area has an additional element of sensitivity attached as the trial information may also be "market sensitive" in that its public disclosure might affect the share price of a publicly listed company.

Contracts with sites involved in clinical trials will contain confidentiality obligations.

Summary
Confidentiality restrictions which apply to clinical trial results must be adhered to. This becomes more sensitive if the results could impact on a company's share price and are deemed "market sensitive."

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