

UP-LRM-WW-005-01

Interactions with Healthcare Professionals

1. Scope

This Policy applies to all Parexel employees, contractors, and third parties (collectively “Representatives”) conducting business on behalf of Parexel who have any form of interaction with Healthcare Professionals (HCPs).

2. Policy Statement

This Policy is to assist you in complying with all applicable laws, regulations, and industry codes associated with interactions with Healthcare Professionals. Where local laws, regulations or codes impose more stringent requirements than those contained herein, the relevant Representatives must comply with the more stringent obligation. Prior to executing a contractual agreement with an HCP, you must **understand the local laws** governing these activities.

A Healthcare Professional (HCP) includes individuals in the health care field who:

- directly interact with patients
- have a role in patient care, diagnosis, or treatment
- have influence over the administration, recommendation, purchase, prescribing, supply, reimbursement, or approval of pharmaceutical or device products.

HCPs include, but are not limited to, physicians, pharmacists, radiologists, technicians, nurses, dentists, medical students, and hospital, clinic, and medical office administrators. Payers are also considered HCPs, as are public officials who participate in public health or social security policies and/or have authority to rule in health-related matters. In some countries, carers/caregivers may also fall under HCP regulations.

HCPs are considered Government Officials when they are employed by, or acting on behalf of, a government owned or controlled institution and you must comply with codes, regulations, and rules for interactions with government officials.

Even if some HCPs are not considered Government Officials in your country there are usually special local laws, regulations, or codes related to the relationship between industry and HCPs. In addition, many clients have special procedures when contracting with HCPs across the world.

Effective Date: 02 Nov 22

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Developed from TP-BPM-WW-006; related to SOP-BPM-WW-001

Printouts of this document must not be copied and should be destroyed confidentially after 24 hours.

3. Principles for Interactions with HCPs

Proper Documentation

All interactions must be conducted and processed in a transparent and open manner. The engagement of any HCP or providing an item of value or benefit to an HCP must be properly documented in written agreements. Expense documentation must be maintained and include the name and address of the HCP recipient, details of the expense incurred, all receipts, and the purpose of the expenditure.

Applicable Laws/Codes

All interactions and activities with HCPs must comply with our Code of Conduct, other Parexel policies, industry standards (e.g., current International Conference on Harmonization-Good Clinical Practice (ICH-GCP), Pharmaceutical Research and Manufacturers Association (PhRMA) Code on Interactions with Healthcare Professionals, Association of the British Pharmaceutical Industry (ABPI) and European Federation of Pharmaceutical Industry Association (EFPIA) Codes of Practice, etc.), as well as applicable laws and regulations (e.g., French Anti-Benefit's law). In the event of a conflict between this Policy and applicable laws, regulations, or industry standards, you must comply with the more stringent obligation.

No Quid Pro Quo

Neither Parexel nor its Representatives may ever offer, give, receive, or solicit something of value to an HCP to **unfairly influence** a business action or decision, such as securing new business, securing approval or keeping an existing customer.

No Circumvention

You must not attempt to circumvent this Policy by authorizing a third party to engage in conduct or interactions which are prohibited by this Policy.

No Spouses/No Guests

It is never appropriate for Parexel to invite or to pay any expense (meals, accommodation, travel expenses, etc.) for the spouse or guest of any HCP who does not have a legitimate interest and role in the business discussion or event at issue. Spouses and guests of HCPs are generally not allowed to attend business events paid for or reimbursed by Parexel or the customer.

No Excuses

It is never acceptable to violate this Policy due to local customs, customers' or competitors' practices, or cultural differences.

Exceptions

Any exceptions, including customer requests, to this Policy must be approved by Parexel's Chief Compliance Officer.

4. Local Laws and Regulations

Some countries require local authority submission for authorization prior to contracting with an HCP. Other countries have pre-approval requirements for certain HCP interactions including: mandating the HCP's employer pre-approval of the contract, or/and a letter from employer authorizing the HCP to provide the service; have a local maximum FMV threshold (rate cap); reimbursement for expenses is pre-determined or restricted.

Prior to executing a contractual agreement with an HCP, you must **understand the local laws** governing these activities as this may result in the need for a significant lead time prior to contracting or fulfilment of services by an HCP. If you are unfamiliar with local or national regulations when contracting with an HCP, it is important to seek local advice in advance.

France: Under the French Anti-Benefit's Law, healthcare companies must submit a prior notice (Declaration) to, or obtain a prior Authorization from, the national authority depending on the amount of the contract value (noting both per hour rate and the full value of the contract reimbursement plus total hospitality expenses are key criteria). The submission to the authority must be via the client's online account and accompanied by certain documents including employer authorization form, HCP contract in local/dual language, and other supporting documents. If a benefit will be provided to a public official (e.g., an HCP employed by a public hospital) the Declaration or Authorization application file must also include an Authorization from the HCP's employer. The French rules cover research, hospitality, engagements, grants and donations, and the definition of an HCP is very broad.

Due to the nature of the timelines, up to 5 month's preparation time is required for certain HCP interactions in France and hence forward planning is necessary. Please refer to the job aid **French HCP Interactions** which outlines the process in detail.

5. Contracting with HCPs

The purpose of engaging HCPs should be to obtain information or advice from medical experts on such topics as the marketplace, products, therapeutic areas, research, or other valid business objectives.

The decisions regarding the selection or retention of HCPs should be made based on the below criteria.

- Be based on a **legitimate** business need that has been identified in advance of requesting the services and before entering into arrangements with prospective HCPs.
- Selection criteria for HCPs are directly related to the identified purpose and the persons selecting the HCP have the necessary expertise to select HCPs meeting the criteria.
- The number of HCPs retained is not greater than the number reasonably necessary to achieve the identified purpose.

- Reasonable compensation at **fair market value (FMV)** which is consistently applied to those engaged for similar services. FMV is the client responsibility. FMV is defined by country, as it depends on the value of services in the **home country of the HCP**, even if the services are being provided out of country. It is important to document how it was determined and to obtain written approval (via email) from client where client does not have an FMV rate card for the country/services.

Rate Caps: Some countries have published a pre-determined maximum FMV threshold for each category of physician which must be used when engaging local HCPs. In addition, compensation for travel time is not allowed in some jurisdictions or, where permitted, it is significantly less than the rate for technical services.

- FMV is based** upon several criteria
 - the HCP's qualification and expertise for the required services
 - the complexity, duration and urgency
 - It should be consistent, and proportional to the services performed.
- It is important to determine if there are any circumstances which could give rise to a potential conflict of interest (Col) between the HCP and the relevant client. The HCP should be required to complete a Col questionnaire (online via Qualtrics or as an appendix to the contract), or similar document, to determine if they have any government position or role that could pose a conflict with the services we/client are asking them to provide. We can minimize most Col risks by asking the HCP to recuse themselves from any decision making for those roles or positions associated with the client. If you are unfamiliar with the Col questionnaire or process, please contact us at Compliance@parexel.com for assistance.
- Must have a **fully executed written agreement** in place describing the specific scope of services and identifying all compensation terms. In order to accurately document the rationale for FMV, the **per hour/day rate** plus the total hours/days to be worked by the HCP must be recorded in the agreement. The contract must be for a **defined, reasonable duration**. The contract should outline the HCP's responsibility to disclose their interest when they write/speak about the matter (transparency requirement to avoid allegations of bias or conflicts of interest). In addition, the contract should be in local or dual language where mandated in local guidance or legislation.
- Must obtain local authority **pre-approval** of the contract terms where required by local laws (e.g., French, Belgium – see Section 4).

Grant Plan is now available for **FMV determination of HCP services** outside of clinical trials & **only** where client does not have a rate card. Submit a ServiceDesk Ticket using the Option:

Support > 07 – CRS > GSS – Grant Plan.

REMEMBER:

- Use the client's FMV rate card when possible
- Parexel established FMV rates **must be submitted to and Approved by the Client.**
- Retain documentation to justify the FMV calculation.

- Is permitted by the **HCP's own employer**. In many countries, the HCP's employer (where a government run institution or otherwise) may be obliged under local laws/regulations to give advance approval of the written HCP contract. Where required, ensure the HCP has received documented prior approval for the delivery of the service from their employer or the employer is a party to the contract if required under local rules (e.g., EU).
- Disclosure requirements regarding potential Conflicts of Interest have been met.
- Is not an inducement or reward for prescribing or recommending a particular medicine or course of treatment.
- Reimbursement for reasonable travel, lodging and meal expenses incurred as part of providing services may be acceptable; refer to Meals, Travel & Hospitality sections of this Policy.
- Documentation demonstrating successful completion of services must be retained, including actual HCP expenses, all receipts, their purpose, and the name of the HCP who incurred the expense.
- Complies with all applicable laws, regulations, and industry codes.
- In accordance with the **client's policies**, where stricter. This may include obtaining advance client approval in accordance with client procedures where a cross-border interaction (HCP service to be provided in a different country to their home country) with an HCP will take place. Some clients use an internal portal to review and approve HCP interactions; access is given to Parexel staff, where relevant.

Do not contract with an HCP if

- The HCP has not been subject to Compliance Due Diligence (CDD) screening by Parexel Compliance.
- The engagement creates a conflict of interest.
- The level of compensation creates a sense of obligation for the HCP to give something in return or is not based on fair market value (FMV).
- The engagement will be used to influence or reward a decision by the HCP that benefits Parexel or the Customer.
- There is not a legitimate business reason.
- Local authority pre-approval and/or employer written approval has not been obtained, where relevant, e.g., France, Germany, some European countries, etc.
- Refuses to execute a contract with a defined scope of work, approved FMV rates, etc.

6. Sanctions

In accordance with our Code of Conduct and Global Sanctions Policy CP819, Parexel and our entities globally cannot do business (directly or indirectly) with, or handle the arrangements for, or communicate with, HCPs or anyone from/in a fully sanctioned country; currently these are Syria, Cuba, North Korea, Iran, and the Crimea, Donetsk and Luhansk regions of Ukraine.

You must also arrange Compliance Due Diligence Screening of any HCP who will provide services to us e.g., advisory boards, meetings, speakers, training, medical imaging reading, BEFORE you contract with them by submitting a Service Desk ticket (Compliance Screening) to request screening.

7. Scientific Events

Some countries require advance approval of the sponsorship of such events (e.g., several European countries such as Belgium, Portugal, Spain), and in addition may also mandate advance approval of sponsorship of HCP attendance as either an attendee or as a speaker. Please familiarize yourself with local rules if you intend to arrange sponsorship of such events (including attendance of HCPs).

7.1 Direct sponsorship of HCP attendance

In many countries this is not permitted under local laws, regulations or codes of practice

7.2 Indirect sponsorship of HCP attendance

In this instance sponsorship of the HCO/institution may be permitted via an Educational grant. The institution will decide which HCPs shall attend. A small number of countries no longer permit indirect sponsorship by healthcare companies.

8. Meals

8.1 Legitimate Meals

There may be legitimate reasons to provide **modest** meals to HCPs and/or members of their staff on behalf of Parexel or our customer, provided they comply with the following rules. All meals provided to HCPs must comply with the following:

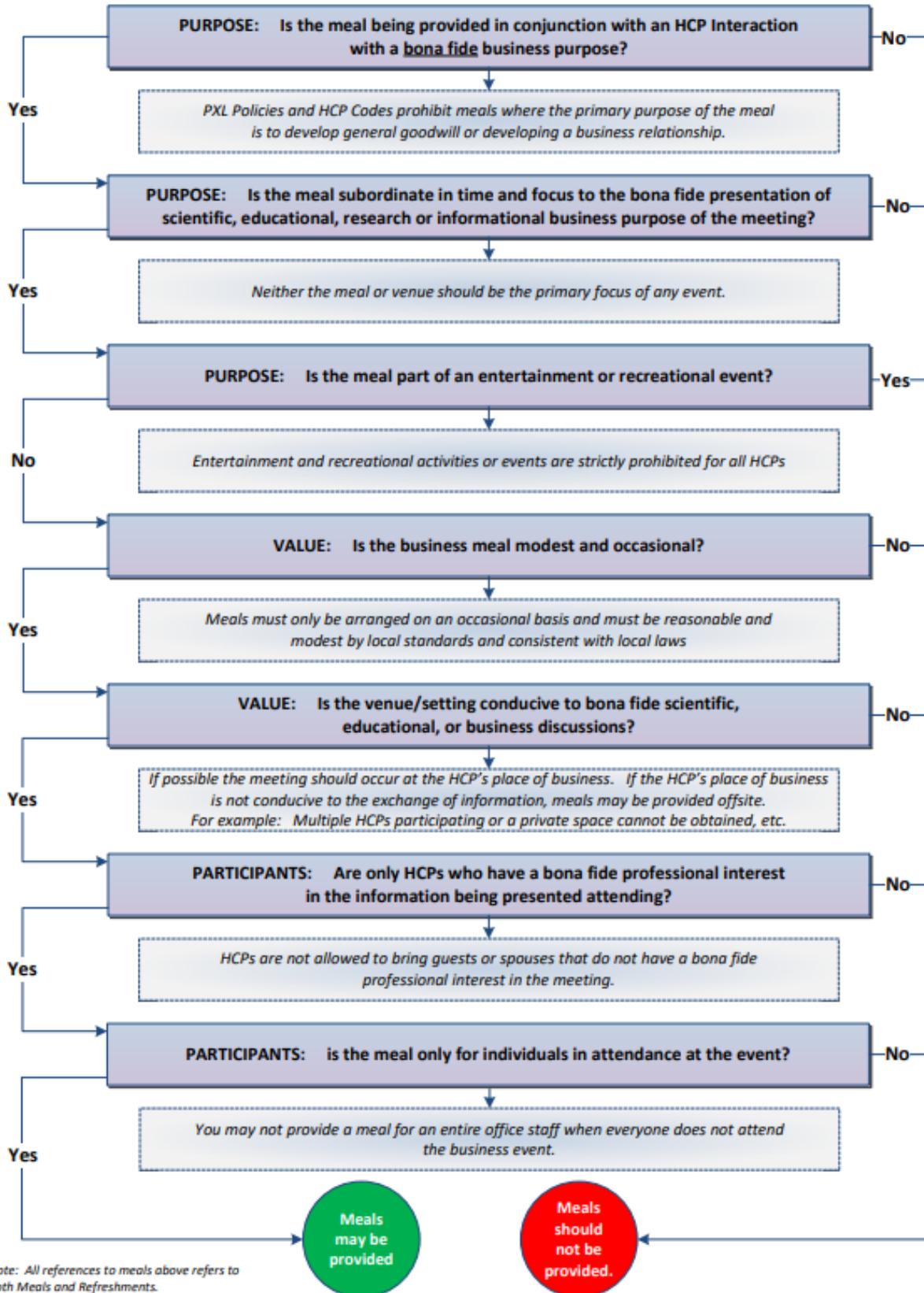
- Be in compliance with applicable legal, regulatory, and industry code requirements. Please check the country meal & hospitality limit based on the meeting location and/or the HCPs home country. The more restrictive limit must be met.
- Be reasonable and modest by local standards and consistent with local laws and ethical business practices.
- Be directly related to a **legitimate** business, scientific or educational activity. An agenda or meeting plan should be documented as well as the reason for the number of HCPs attending.
- Be arranged only on an occasional basis as part of a bona fide exchange of scientific, educational, or business information.
- Take place at a time, venue, and manner conducive to conducting business or sharing of business, scientific or educational information.
- The venue must be appropriate and not extravagant or renowned for its entertainment facilities.
- Both the host and receiver must be present at the business meal.
- If alcohol is consumed, it should be consumed in moderation and included within the meal limits.
- Parexel's payment for the meal must be permitted by the recipient's own institution/employer policies and/or customer's policies if the meal is provided on behalf of our customer.

8.2 Prohibited Meals and Hospitality to HCPs, without limitations

- Lavish or excessive meals.
- Celebratory and goodwill meals, or those with no legitimate business purpose, e.g., educational.
- Entertainment and recreational activities or events.
- It is never appropriate to pay for any meals incurred by spouses/guests of HCPs, or anyone lacking a legitimate interest in the business event. Such individuals must not be permitted to attend any part of the business meeting.

8.3 HCP Meal Decision Tree

Illustrative Meal / Refreshment Decision Tree



9. Travel and Hospitality

We may only pay for travel and accommodation costs incurred by an HCP in connection with legitimate business, scientific, or educational activities. These can include consulting, speaking services, meetings, and conferences consistent with applicable laws, regulations and codes as defined below:

- Modest and reasonable travel and accommodations can be provided to an attending HCP but only when there are valid reasons to support the need for out-of-town travel.

For international events, Representatives must ensure travel, hospitality, meals, and selected locations comply with the hospitality regulations for each HCP for their respective country **and** are consistent with the regulations for the event country location. This may include employer approval of HCP hospitality.

In case of a conflict, stricter requirements shall always apply.

- The selected geographic location should be convenient to most attendees and must never be the main attraction of the event. The selected time of year must not be purposely scheduled during a tourist season for the selected geographic location.

- Provide reasonable travel and hospitality costs for required attendees. The expected class of

airline travel is economy or standard. Business class may be acceptable for flights greater than six (6) hours or for special circumstances with consistently applied parameters.

- It is never appropriate to pay for any travel or hospitality costs incurred by spouses/guests of HCPs, or anyone lacking a legitimate interest in the business event.
- Maintain written documentation describing the meeting purpose, dates and location, meeting agenda, and names of attendees. Maintain sign-in sheets or other confirmation of attendance. If required, obtain pre-authorization from Parexel management or the customer.

10. Gifts

We can **never** give or accept any gifts to/from any HCP or his/her staff member(s) on behalf of Parexel or a customer. Staff of an HCP must be treated as an HCP.

A gift is an item, meal, or anything of value that is intended to benefit an HCP and is not associated with a legitimate business, scientific or educational purpose.

Examples of Prohibited Gifts/Items

- Non-educational, promotional items (pens, notebooks, notepads, mugs, etc.).
- All items intended for the personal benefit or entertainment of the HCP, regardless of their value or of an upcoming national holiday (e.g., gift baskets, flowers, wine, theatre tickets, concert tickets, artwork, golf game, golf bags, clothing, etc.).

Parexel employees or representatives may request an exception by submitting a written request to Compliance at Compliance@parexel.com.

Exceptions to these gift requirements must be approved by Parexel's Chief Compliance Officer, or designee, in advance.

- Goods recognizing a life-event such as a wedding, birth, or birthday
- Cash or cash equivalents, even if of low (nominal) value, such as vouchers, gift cards, on-line currency, etc.
- Items capable of being used for educational and non-educational purposes, such as, iPad, camera.
- Items that are raffled or given away (including at trade shows) that are not considered educational items.
- Non-educational items primarily designed for patient treatment (e.g., medical equipment such as stethoscopes) or for patient use (e.g., pedometers, stopwatches, other general fitness items).

11. Transparency Reporting Obligations

Anyone who is involved in providing a payment or any transfer of value (ToV) (such as supplies, equipment, meals, travel expenses, etc.) on behalf of our clients to any Healthcare Organization (HCO) or HCP needs to be aware of our Transparency Reporting obligations. Under laws and regulations, like the United States (US) Sunshine Act and similar laws and regulations in the European Union (EU), United Kingdom (UK) and other countries, pharmaceutical/healthcare companies must publish details of such payments and ToVs.

- Services performed must be properly documented and confirmed they have been satisfactorily completed before payment is approved & processed.
- Invoices should clearly document the services completed per the terms in the contract.
- Associated travel, lodging and meal expenses must have supporting receipts and must not include payments for any side trips, unrelated trip extensions, entertainment or expenses for individuals who are not providing contracted services.
- All payments must be processed through Parexel Accounts Payable system to ensure we maintain proper books and records and are transparent in all HCP payments.

It is critically important that all HCP payments and ToVs are processed in a manner that will allow Parexel to track each payment or ToV **and the HCP that benefited from it**. This ensures the accuracy of reports to clients and allows the client to fulfil their legal obligations associated with transparency regulations.

Below are the most common types of payments and ToVs (not exhaustive):

- Consulting fees
- Investigator fees
- Honoraria fees, incl Advisory Boards
- Food & beverages
- Travel & lodging
- Research expenses paid to PI or Site (advertising, labs, local IRB fees, etc.)
- Copyright fees for articles/papers
- Equipment
- Supplies
- Speaker fees
- Charitable contributions given in lieu of payment to HCPs

Additional information regarding transparency reporting can be found in the Compliance SharePoint site: [Transparency Reporting](#).

12. Market Research and Outcomes Research

Market research carried out by HCPs on behalf of Parexel’s customers is usually **double blinded** (i.e., both the HCP and the pharmaceutical customer are unaware of the other’s identity). For this reason, most market research payments are typically out of scope of transparency regulations. Non-blinded market research does fall under transparency reporting requirements and must comply with Section 9. Please note that Data Privacy requirements mandating identification of the data controller to the HCP (after the research is concluded) may mean that the ‘unblinding’ qualifies for transparency reporting.

Exceptions: In France, double blind Market Research is currently not exempt from the French Anti-Benefit’s law submission process or from the local Transparency (local Sunshine Act) reporting law.

Employer Authorization: Employer authorization and other limitations exist in several other countries when recruiting HCPs for such research. Please refer to the current European Pharmaceutical Market Research Association (EPHMRA) Code of Conduct for guidance on global requirements by country.

FMV: Market research carried out by Parexel on our own behalf must meet the requirements of Fair Market Value and follow the Rules outlined in this document.

HCPs participating in Advisory Boards, open panels or similar do not qualify as market research and must be considered a ‘fee for service’ within the scope of this Policy and require transparency reporting.

Additional detail regarding market and outcomes research is outlined in SOP-AC-WW-001: Market Research Interactions with Healthcare Stakeholders and in SOP-AC-WW-002: Outcomes Research and Interactions with Participants.

US State Limitations on using US HCPs: The following states currently have limitations that prohibit the use of HCPs for many types of Market Research and Parexel should not carry out Market Research on HCPs in these states at this time:

- Vermont
- Minnesota

13. HCP Compliance Due Diligence

CDD screening of HCPs is a vital component of our compliance program. CDD is performed by the Compliance team and determines whether an HCP is named on a restricted, denied, debarred, designated, blocked party, or politically exposed person list.

Before engaging in any commercial relationship or transaction with any HCP, CDD Screening must be performed; this means you must obtain approval of the HCP by the Compliance Due Diligence team **prior to contract execution and commencement of services.**

Please submit a Service Desk ticket (Compliance Screening, option 14), or contact the Compliance Due Diligence team within the Compliance department for assistance with due diligence screening **before** engaging any HCP at: FCPA-OFACCompliance@parexel.com.

14. Reporting Violations

Anyone who suspects or is aware of a violation of this Policy must report the issue. Colleagues may contact Compliance at Compliance@parexel.com or through the [Ethics Hotline](#).

15. HCP Interaction FAQ

For additional guidance, please read our HCP Interaction FAQs [here](#).

16. RASCI Chart

	Chief Compliance Officer	SBU / BU Head	Employee
Creation and revision of Policy	A/R	C _i	
Monitoring compliance with this Policy	A	C _i	
Enforcement of Policy	A/R		
Compliance with Policy			R

Legend:

- R - RESPONSIBLE** Person/people who are/will be responsible for implementation of the decision
- A - ACCOUNTABLE** Individual who has ultimate authority/responsibility to make a decision
- S - SUPPORT** Individual who supports process activity
- C - CONSULTED** Person/people whose input/opinion is required for the decision
- C_i -** CONSULTED for input
- C_a-** CONSULTED for agreement
- I - INFORMED** Person/people who need to know of the decision

17. Referenced Documents

Document Number	Document Title
CP 819	Global Sanctions Policy
SOP-AC-WW-001	Market Research Interactions with Healthcare Stakeholders
SOP-AC-WW-002	Outcomes Research and Interactions with Participants
	Code of Conduct

18. Related Documents

Document Number	Document Title
	HCP Interaction FAQs
	French HCP Interactions – Job Aid

19. Revision History

Code Version:	005-01	Effective Date:	02 Nov 22
Policy Owner:	Marty Mahoney	Replaces Document:	New
Responsible Unit:	Compliance and Ethics	Active Country / Region / Unit:	Worldwide
Summary of Change:			
<ul style="list-style-type: none"> New Unit Policy that replaces Rules for Interactions with Healthcare Professionals (an Uncontrolled guideline, previously linked from our Code of Conduct) <p>Summary of changes:</p> <ul style="list-style-type: none"> Use of the Unit Policy template Reference to local laws and regulations including pre-determined maximum FMV, expenses, and other national rules regarding pre-approval of HCP contracts etc. Additional details regarding FMV calculation including reference to local rate caps and requirement to indicate the hourly rate and reference to use of Grantplan to determine FMV (but only where client does not have a rate card). Noting client written approval (via email) is required where Parexel determine the potential FMV. Additional details regarding content of the written agreement/contract with an HCP Reference to national laws requiring pre-approval of HCP interactions (e.g., French Anti-Benefit's Law, etc.) Reference to client policies on cross-border interactions with HCPs and their approval requirements Reference to the requirement for pre-approval of an HCP's contract by an employer – this is mandated in several countries, particularly for government institutions Insertion of Sponsorship of Scientific Events (including HCP attendance as a speaker) Insertion of Market Research (MR) and Outcomes Research (OR) & cross-reference to the MR & OR SOPs Minor rewording, etc., to improve clarity & comprehension 			
Associated Documents:			
New	None		
Updated (Changes made)	None		
Retracted (Removed)	None		
Obsolete (Replaced)	None		

UP-LRM-WW-005-01: Rules on interactions with Healthcare Professionals
 Effective Date: 02 Nov 22

Confidential

Developed from TP-BPM-WW-006; related to SOP-BPM-WW-001

20. Deviations

Applicable deviations to this Policy may be accessed in the Deviations area of the Controlled Documents Library (CDL).	
Location: PMED	Responsible Administrator: BPM Representative

21. Storage

Storage of Original Document	
Location: PMED	Responsible Administrator: BPM Representative

22. Signatures

Policy Owner Delegate/Subject Matter Expert	Signatory
	Christine Kiezulas Vice President and Deputy Chief Compliance Officer

Authorization by Policy Owner	Signatory
	Marty Mahoney Senior Vice President, Associate General Counsel and Chief Compliance Officer

PAREXEL International Electronic Signature Page

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Title: , Legal and Risk Management
Date: Wednesday, 02 November 2022, 11:43 AM GMT Standard Time
Meaning: Document content approved.

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Title: , Legal and Risk Management
Date: Wednesday, 02 November 2022, 12:08 PM GMT Standard Time
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