UP-PSE-WW-001-01

Guideline on Interactions with Patients and Patient Advocacy Groups

1. Scope

This policy applies globally to all Parexel employees, contractors, and third parties (collectively "Employees") who have any interaction with individual patients and/or Patient Advocacy Groups (PAGs).

Interactions with Patients and PAGs can include, but are not limited to, research collaboration, consultancy, and services (e.g., advisory boards). These activities may include payment of expenses, charitable donations, corporate sponsorship, or other non-cash benefits.

1.1 Interactions with patients/ PAGs fall into two categories

- Non-client supporting interactions. These interactions aim to strengthen the PAGs, support their members, enhance their empowerment, provide education to patient communities, and improve awareness of clinical research. It strengthens Parexel patients first strategy and provides us with a better understanding of the patient experience.
- Client supporting activities. These activities are on behalf of clients who are Pharmaceutical/ Device companies and who have contracted Parexel. As we act on behalf of the client we must comply with all codes and regulations that apply to the Healthcare and Pharmaceutical industries. Parexel must follow all client policies (when available) and not our own when interacting with patients/patient advocacy groups on behalf of a client.

2. Policy Statement

As a global organization, Parexel is committed to conducting business in an ethical and professional manner consistent with applicable laws, regulations, and industry codes on the relationship between the pharmaceutical industry, patients, and patient groups. We must follow all such laws and codes that apply to your interactions with patients and their representatives (healthcare charities, patient associations, patient organizations, patient communities, patient influencers and PAGs).

This document outlines key patient engagement principles, rules, and recommendations for collaboration. Compliance with these guidelines demonstrates our commitment to integrity in our operations and builds trust with patients, their representatives, and our clients. The principles are based on the requirements set out by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA) guidance, and the Patients Active in Research in Improvements and Dialogues for an Improved Generation of Medicines (PARADIGM) Code of Conduct which was developed under the Innovative Medicines Initiative (IMI) Joint Undertaking 2 (see Section 10 References).

Where local laws and regulations impose more stringent requirements, the relevant Parexel employee or representative must comply with the more stringent obligation.

Before you consider working with a PAG or patient advisor you must contact Parexel's dedicated Patient Partnerships Team (+pagengagementservices@parexel.com), as all interactions with patient advisors/PAGs on behalf of Parexel and clients need to be managed and coordinated by this specific group.

If you have any questions, are unsure how to interpret or apply these guidelines, or have an issue not addressed by this guideline, do not hesitate to seek guidance from the Global Compliance Department at Compliance@parexel.com.

3. Definitions

Patient Advocacy Groups (PAGs)

PAGs may also be referred to as patient associations, online patient communities, patient organizations, patient communities, healthcare charities, disease groups or patient groups.

Their aim is to improve the lives of people with a particular disease or medical condition. They educate, advocate for, provide support services to patients, their families, and their care partner/care partners. They campaign for better standards of care and access to treatments for the patients they represent, as well as raise money to fund research and lobby government and regulatory agencies.

PAGs are generally non-profit entities or/and registered health charities. They vary in size and complexity; from large, complex with paid employees to small volunteer run groups.

Patients

Patients collectively refers to patients, potential patients, family members, and their care partners.

It includes the following:

- **Lived Experienced Patients**: are individual patients with personal experience of living with a disease. They may or may not have heard about clinical trials before but have no significant practical experience of them
- **Expert Patients**: In addition to disease-specific expertise, have knowledge in clinical research aspects through training, research, or experience
- **Professional Patients**: Have knowledge about the condition beyond individual/personal experience and in clinical research aspects. This patient is skilled in public speaking and seen as a subject matter expert and often works in a full-time capacity as a patient advocate
- **Patient Thought Leaders**: Have knowledge about the condition beyond individual/personal experience and in clinical research aspects. This patient is skilled in public speaking and seen as a subject matter expert and influencer (e.g., high social media presence and high number of social media followers) by other patients with the same condition
- **Care Partners** support individual patients and include family members, as well as paid or volunteer helpers.
- **Patient Group Representatives** are mandated to represent and express the collective views of a patient group on a specific issue or disease area.

Fair Market Value

Fair Market Value (FMV) is the commercially reasonable price that a company customarily would pay for a particular service/activity to be provided by a patient/PAG and considers the nature of the service/activity, the qualifications and expertise of the person assigned to perform the service/activity, and the residing country of the patient/PAG. The FMV will therefore vary by country and provider for the same service/activity.

Transfer of Value

Any Transfer of Value, whether monetary, a benefit in kind or otherwise, including payments of fees for services, sponsorships/donations, travel, and the provision of hospitality.

4. Parexel Guiding Principles

The **Guiding Principles** are based on the requirements set out by IFPMA, EFPIA and PARADIGM and must serve as the basis for any interaction with a patient/PAG. They include ethical principles as well as general principles.

When interacting with patients/PAGs Parexel must adhere to the following general principles:

- All interactions with patient advisors/PAGs must be coordinated by the Parexel Patient Partnerships Team. Contact the team at +pagengagementservices@parexel.com before you consider working with a PAG.
- All interactions or contact with patients/PAGs must be in accordance with this Policy and prioritize the best interests of the patients.
- Compliance with regulations and guidelines: All interactions and activities with patients/PAGs must comply with local law or national regulations (e.g., Food and Drug Administration (FDA)), applicable industry codes (e.g., EFPIA, etc.), and Parexel Policies. In the event of a conflict between this guideline and local law or industry standards, the relevant Parexel employee or representative must comply with the more stringent obligation.

The following key ethical principles apply:

Integrity

- Parexel operates with integrity and acts ethically and responsibly in accordance with our Code of Conduct. All interactions with patients and PAGs must be able to withstand external scrutiny (for example by external auditors or journalists). All interactions should be based on mutual respect; this includes respecting the rights to privacy of patients and care partners.
- Individual patients: You must seek advice from the Parexel Patient Partnerships Team (+pagengagementservices@parexel.com) before contacting an individual patient, as direct contact with patients may be restricted by local law, particularly when we act for or on behalf of clients.
- Parexel must not reach out to individual patients unless the patient has previously expressed interest in being contacted or has provided his/her consent hereto. However, direct contact with PAGs or their representatives is permissible, provided it follows the principles of this document and is coordinated and overseen by the Patient Advocacy Manager when proposing to work with PAGs.

Respect & Diversity

- Parexel shall communicate with and treat all involved with the same respect and courtesy, with special attention to non-discrimination. No patient can be discriminated against for reasons of health literacy nor lack of training nor by the fact that processes need to be adapted to their needs and capacities to ensure their meaningful involvement. Parexel shall endeavor to support diversity (disability status, gender identity, race, ethnicity, gender, or other underrepresented community member) and shall include vulnerable/underrepresented patients, where possible.

Beneficence

- All activities are performed with the common goal of benefit to patients.

Equality

- Parexel shall treat all involved stakeholders as equals.

Data Protection and Privacy

We process the personal data of patients and protect their rights to privacy consistent with applicable local laws and regulations:

- We must clearly inform patients how their personal data will be used and use plain English (or local language) in contract/consent forms to state how their personal data and rights to privacy will be protected.
- We only collect personal data we need for our specified purposes, and we have sufficient personal data to properly fulfil those purposes; we also periodically review the data we hold and delete anything we don't need.
- Note that health information is considered sensitive personal data in many jurisdictions and has higher standards of protection. We must limit the collection of sensitive personal data where possible.
- Data protection and privacy clauses will be captured in the patient advisor consultancy agreement and the processing of patient advisors' personal data by Parexel will be for the purpose of participation as a patient advisor in support of Parexel's clinical research activities.

- Where Parexel acts as a data processor, unless the data processor being regulated directly by local laws, the data controller's instructions should be followed strictly, and the contract should clarify the data controller's name.
- All efforts must be taken to protect patient confidentiality regarding their health conditions and personal patient stories. For more information on Confidentiality of Patient Information refer to section 4.3.

Transparency of Purpose

- The purpose and the desired outcome of any interaction with a patient/care partner/PAG(s) must be clear, open, and transparent to both parties from the outset. Parexel colleagues must, from the beginning, make their affiliation clear to the patient/care partner/PAG, and, for meetings, agenda with scope and minutes should be made and circulated between the parties.
- The purpose of an engagement with a patient/care partner/PAG must always be based on a legitimate need for service or advice, or a legitimate interest in supporting the PAG's mission. The purpose must be detailed in a contract between Parexel and the patient/PAG.
- This principle will set clear expectations for the interaction and avoid any undue influence on a patient/care partner/PAG.

Fair Market Value (FMV)

- It is fair and just that patients/care partner are remunerated for their work time, experience, and expertise. We compensate patients, care partners and PAG representatives in line with FMV for services provided. This remuneration should be based on FMV as this ensures consistency in the way Parexel remunerates patients, care partners and PAGs and avoids any undue influence on a patient/care partner/PAG. FMV will be determined by the Parexel Patient Partnerships Team using Parexel FMV calculator. Patient advisor/PAG contracts and payments will be managed by the Parexel Patient Partnerships Team.
- Parexel will not limit or restrict PAGs in their interactions and partnerships with Pharma or other Clinical Research Organizations (CROs). Any Transfer of Value (ToV) made to a patient/PAG must be reasonable, appropriate and reflect FMV. Noting that it is preferable to contract with a PAG rather than with individual representatives of the PAG.
- When Parexel contracts with patients/PAGs on behalf of clients we should use the client's Rate Card for determining FMV.

Transparency in our Relationships

- Parexel shall be transparent in its relationships with patients, care partners and PAGs in line with applicable laws and regulations, pharmaceutical industry associations guidelines and with the PAG's own governance requirements and transparency rules.
- Always disclose that you are a Parexel employee or representative when interacting with or meeting patients, care partners and PAGs.
- Global internal transparency within Parexel must be established to ensure consistency in remuneration/compensation and enable us to ensure that the patient/care partner/PAG is not becoming dependent upon financing by Parexel, in conflict with the principle of independence.
- The principle of 'Transparency' will ensure that the public acknowledges the legitimate intent of the engagement between Parexel and a patient/care partner/PAG and that any conflict of interest is avoided.

Disclosure of Payments

- For PAGs, the details of each engagement shall be made publicly available according to local laws, regulations, and industry codes on disclosure/transparency. This may include both transparency requirements imposed on the PAG, and transparency requirements imposed on pharmaceutical companies and other stakeholders.
- Suggested minimal practice is a publication of the payment/transfer of Benefits in Kind by both Parexel and the PAG on their respective websites. When we work with PAGs in our own right (and not for clients) we should agree to the text and financial and non-financial data that will be published on the Parexel.com website (captured in the annual Parexel Environmental, Social and Governance report) and the PAG's site, this coordinated approach ensures both parties can confirm the accuracy of the declaration.

- When we work for clients, we must routinely make the payment data available to the client to facilitate their own reporting of such engagements with PAGs. Parexel does not make any declarations of payment data when we work for the client.

  Parexel sponsorships and donations to PAGs and a summary of the Parexel Patient Advisory Council interactions are captured in the annual Parexel Environmental, Social and Governance report which is published on https://www.parexel.com.

Independence

- No interaction may compromise the independence of the patient, care partner, or PAG. In addition, Parexel commits to independence of our contributions from decisions and strategies arising out of the interests of Parexel. The patient, care partner, or PAG should not be primarily dependent upon financing by Parexel, and we must not restrict the patient, care partner, or PAG from interacting with other stakeholders or competitors. Parexel encourages patients, care partners and PAGs to seek other revenue sources to ensure their independence.

No Promotion

- There is a strict prohibition on promoting prescription only and pre-approved medicines towards the public, which includes patients and PAGs, applicable all over the world which must be adhered to. Solely in the United States of America (USA) and New Zealand, Direct to Consumer promotion is permitted.
- An engagement with a patient/PAG must never be undertaken to promote our clients' products or therapies, either directly or indirectly. It is important that no engagement is perceived as an inducement to recommend medicinal products or therapies. It is acceptable to engage with a PAG to drive awareness of a clinical trial.
- We do not provide anything of value to influence patients' use or recommendation of therapies, treatments, medicinal products, devices, or health solutions.

Social Media

Due to the prohibition on promotion of prescription only medicines and pre-approval medicines towards the public in most countries, Parexel employees must not engage in social media posts (including reposting, liking, or tagging) concerning client products, treatment options, therapies, etc. Contact Compliance@parexel.com if you have questions or Corporate Communications.

4.1 Practical Rules

Proper Documentation	All interactions must be conducted and processed in a transparent and open manner. The engagement of any patients, care partners or PAGs, the provision of financial support, in-kind contribution, an item of value or a benefit to patients must be properly documented in written agreements, in compliance with Parexel Policies and state, federal, and national regulations. The contract must set out the nature of support, including the purpose of any activity, the timeframe for the support and its funding. Contracts for patients and patient advocacy groups will be managed by the Patient Partnerships Team. For Parexel supporting interactions: Parexel contract templates should be utilized For client-related activities: It is essential to solicit the contract and CDA requirements from clients in advance and to determine the requirements for using the Parexel contract templates or the client's own contract templates. *Note: Please refer to the guidance information on Interactions with Patients and Patient Groups as mentioned in the Related Document Section.* Documentation of all expenses must include the name and address of the recipient, the details of the expense incurred including all receipts, and the purpose or reason for the expenditure. This may be provided via an invoice or by a completed honoraria form (provided by the Patient Partnerships Team)
Hospitality	Any transfers of value (e.g., meals, snacks, refreshments) at events and meetings must comply with Parexel rules on hospitality regarding business meals. CP 820 Gift and Hospitality Policy
Care partner	Many patients may be unable to travel or participate without the presence of their care partner. Participation of a care partner at an event, where justified by the patient's health condition or age, is acceptable. Other guests or spouses are not permitted at business meetings or associated hospitality. If a care partner is acting in the capacity as an advisor to Parexel (similar to a patient advisor), Parexel will provide compensation in line with the patient advisor FMV rates. If a care partner is acting in a support capacity to a Parexel contracted patient advisor, Parexel will cover the expenses for the attendance of the care partner (to the same level as the patient advisor they are accompanying) but no compensation payment will be provided to care partners.
Parexel use of social media related to PAGs, client products, therapeutic-area-related or any medicinal products. Excluded from this rule are over the counter (OTC) products and non-medicinal products/devices	Parexel colleagues intending to participate in online groups or who are active members of PAGs in disease areas where Parexel or our clients are active, **must obtain approval in advance** by and report existing roles to our Global Compliance Department (Compliance@parexel.com). All communications must be transparent. Social media posts associated with PAGs, medicinal products, or therapeutic-area-related activities by any employee must be approved by Global Communications in advance. Client related social media posts by Parexel employees are **not permitted** due to risk of infringing local codes or legislation concerning pharmaceutical or device companies.

Product safety	When we work with patients/care partners/PAGs on behalf of clients we must immediately report adverse events and other experiences, including product quality complaints, that patients experience in using the clients' products according to the relevant pharmacovigilance and complaint reporting requirements. It is essential to solicit the reporting requirements from clients in advance and ensure staff are trained on these requirements **prior** to engaging in work with patients/care partners/PAGs
Confidentiality	Confidentiality Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA) must be in place with patients/care partners/PAGs before any discussion on planned activities which may involve discussions on forthcoming trials, specific products or when we share any client generated documents (e.g., surveys created by clients). In addition, a PAG contract (using the approved Parexel PAG CDA template) must be put in place when services are to be provided, regardless of payment For Parexel supporting interactions: Parexel PAG contract template should be utilized For client-related activities: It is essential to solicit the contract and CDA requirements from clients in advance and to determine the requirements for using the Parexel PAG contract templates or the client's own contract templates. Contract templates are held by the Patient Partnerships team and all contracts/CDA are managed by this group.
Information provided	Any information to be provided to patients/care partners must be approved in advance by clients, Medical, Legal, & Regulatory (MLR) and receive Institutional Review Board (IRB)/Independent Ethics Committee approval. Any therapy, device or product information supplied must be consistent with client's product labelling, truthful and not misleading, supported by substantial evidence, and appropriately balance product risks and benefits. Any general information on clinical trials to be provided by Parexel in their own capacity must be reviewed and approved by Parexel Legal, Compliance, Medical and Regulatory Subject Matter Experts (SMEs).
Transparent	Always disclose that you are a Parexel employee or representative when interacting with patients/care partners/PAGs. You must also disclose when you are acting on behalf of a client.
Avoidance of medical advice	We respect the independence of patients, care partners and PAGs and do not provide medical advice or exercise any undue influence on their views and decisions. Regardless of your professional training or position within Parexel, never recommend or compare products or therapies, never discuss off-label uses of a product with a patient/care partners and/or PAGs and never provide medical advice. Never respond to patient/care partners and PAGs questions regarding medical treatment or other requests for medical advice. Always refer the patients, care partners and PAGs to their healthcare provider.

Clinical trial enquires	Parexel respects the independence and confidentiality of patients, care partners and PAGs. Parexel Employees **must not engage with individual patients directly** and should never provide clinical trial recommendations, medical advice or exercise any undue influence on their views and decisions. Patients must **never be advised to contact Parexel Employees directly** regarding a clinical trial enquiry.
Exceptions	Any exceptions, including client requests, from these guidelines must be approved by Parexel Compliance CCO at Compliance@parexel.com.

4.2 Discussions Regarding Insurance Coverage in the USA

Parexel employees must not have discussions with patients living in the United States (US) regarding insurance coverage or reimbursement for products based upon a patient's specific circumstances.

4.3 Confidentiality of Patient Information

Parexel must keep patient health information and personal data confidential.

Parexel employees should try to avoid receiving specific patient health information, avoid discussing specific patient health information and avoid receiving and retaining private individual information.

Colleagues should be aware that patients may volunteer unsolicited health or other confidential information; if you encounter a patient's health information during an interaction, the information may not be used or disclosed for any purpose or in any matter that would compromise its confidentiality.

Enquires from individual patients regarding clinical trial recommendations

Parexel respects the independence and confidentiality of patients, care partners and PAGs and does not provide medical advice or exercise any undue influence on their views and decisions. Parexel employees must not engage with individual patients directly and should never provide clinical trial recommendations to individual patients directly.

In some instance, Parexel may be interacting with and providing information on a clinical trial to a PAG representative who is an individual patient – these types of interactions are permitted since the information provided is not intended as a specific recommendation to the PAG representative.

- If a Parexel employee receives an enquiry from an individual patient requesting recommendations for or information on a clinical trial, they should respond as follows
    - Explain that due to patient confidentiality and data protection requirements, we cannot engage with patients directly and we cannot provide medical advice
    - Refer patients to the following three sources of information on clinical trials
        - Their Healthcare provider
        - www.clinicaltrials.gov or local equivalent
        - Center for Information and Study on Clinical Research Participation, Inc.'s (CISCRP) at www.ciscrp.org/services/search-clinical-trials

Providing information to patients and patient advocacy groups on clinical trials

Patients must never be advised to contact Parexel employees directly regarding a clinical trial nor should they be provided with the contact details of Parexel or our employees. Patients should be directed to www.clinicaltrials.gov or local equivalent for further information on a clinical trial. Patients should then follow the guidance outlined on the clinicaltrials.gov website if they are interested in a trial (https://clinicaltrials.gov/ct2/help/for-patient). Patients should consult with their healthcare professional regarding participating in a clinical trial and they or their healthcare professional should contact the study clinic research staff and ask questions about the specific study. Contact information for study clinic research staff can be found in the *'Contacts and Locations'* section of the study record in www.clinicaltrials.gov if that study is active or recruiting participants.

Clients may have specific guidance on clinical trial postings on PAG websites and these must be adhered to. Clients may also have their own clinical trial websites which provide details of ongoing trials and contact information for patients interested in a specific trial. These websites may be referenced, upon approval from the sponsor, in postings for PAG websites.

Information provided to patients or PAG on a specific clinical trial must be based on IRB)/ IEC approved content (if available) or adapted from the www.clinicaltrials.gov or local equivalent listing, ensuring the original intent of the content is maintained. Postings must be approved by the Sponsor's Medical, Legal, Regulatory (MLR) team prior to use and content must be IRB/EC approved.

Trial listings on www.clinicaltrials.gov or other listing websites (for example: National Cancer Institute's cancer clinical trial listing) do not require IRB approval. However, there should be no additional text inserted and no reference to free medical treatment as otherwise IRB/IEC approval is required.

Refer to SOP-SRD-WW-001 Authoring of Scientific and Regulatory Documents for information on the full process.

Parexel employees

When we engage with Parexel employees as patients, we must take additional care to ensure that they consent to the sharing of sensitive health data. Engagement with Parexel employees as patients falls within the remit of the Parexel Patient Community and the 'Guiding Principles of the Parexel Patient Community' must be adhered to (https://pxlcrs.my.site.com/patientcommunity/s/).

Engaging Third-party Vendors

Parexel colleagues who engage a third-party vendor who will support Parexel (or our clients) (for example patient insights vendors, patient survey providers, patient clinical outcome assessment vendors, market research vendors) when we interact with patients or PAGs are responsible for:

- Communicating this guidance and its requirements to the third-party vendor. A link to this unit policy will be included in the supplier qualification form to confirm the vendor understanding of and compliance to the policy
- Confirming the third-party vendor understands the requirements
- Ensuring oversight and monitoring of the third-party vendor to verify compliance with Parexel's requirements, and
- Escalating instances of suspected non-compliance to the Parexel Global Compliance Department at Compliance@parexel.com.

5. Engaging and Contracting with Patients

5.1 Fee-for-Service Arrangements with Patients

Parexel may enter fee-for-service arrangements with patients/care partners for bona fide services for which Parexel or a client has a legitimate business need. The engagement must be based on a written contract containing clear tasks and responsibilities, compensation, and confidentiality stipulations and in accordance with the contractual framework (see section 7.1). Fees and expenses must be reasonable and FMV in relation to the services rendered. When working for a client use their FMV rate card.

Patients may be contracted directly or via their PAG in which case the services would be arranged and contracted with the PAG. Parexel respects the rights and wishes of patient advisors and understand that, in certain cases, a patient advisor may wish for their individual payment to be processed as a charitable donation. Requests for payments in the form of charitable donations must be documented in the patient advisor contract and with the approval of the client.

While the level of remuneration, including its methodology, is an internal client decision, pharmaceutical companies should consider several factors in determining the appropriate remuneration in accordance with justifiable FMV, including:

- Individual expertise: level of experience, prior training, or experience relevant to the service provided, attendance at previous scientific meetings, transferable skills relevant to the engagement
- Complexity of the tasks assigned, for example international vs national meetings
- Total time invested: including preparatory time, length of the engagement

- Country of residence – taking national cost of living index (e.g., Gross Domestic Product (GDP) level) into consideration
- Travel time can be compensated

Fee-for-services agreements with Patients/Care partners may include, but are not limited to the following:

- Advisory Boards and Focus Groups: The purpose of engaging patients, care partners (or Consumers) as consultants and/or members of Advisory Boards or Focus Groups is to receive specific, knowledge-enhancing information and advice. Patients who are engaged for services must have experience with a specific disease and/or its treatment and/or the care of such patients.
- Speakers: The purpose of engaging patients to speak at events is to share relevant experiences.
- Market Research: The purpose of engaging patients for Market Research is to determine patient perceptions and opinions on their relevant experiences.
- Patient insights: Patients or care partners could be engaged for the purpose of obtaining feedback on protocol designs; gaining a better understanding of life with disease
- Bloggers/Social Media Influencers: Parexel may engage patients/care partners to post unbranded disease state information or study-branded information regarding participation in clinical research on online blogs or social media pages. Patients/Care partners posting online must disclose that they are posting on behalf of Parexel or by posting on a Parexel site (e.g., Parexel's social media page). Patients/care partners who are engaged to post information online on behalf of Parexel must be trained on the local legal requirements and codes and Parexel's social media guidance.
- Patient spokespersons: Spokespersons may be engaged to provide unbranded disease state information or branded promotional messages for clients, or information regarding participation in clinical research. Spokespersons must disclose that they have been engaged by Parexel or/and/or the client. Spokespersons delivering or supporting unbranded disease state messaging must not discuss clients' products or make product claims. Patient/care partner spokespersons who deliver branded messages about client products must have used the relevant product/therapy directly.
- Other services: Other services could include user testing or anecdotal input, scientific or methodological competency.

5.2 Fair Market Value (FMV)

Generally, patients, care partners and PAGs can be compensated in the form of actual payment for services being provided to Parexel/client. No remuneration must be offered for time spent by a patient/care partner/PAG representative at an activity where the patient/PAG is not specifically delivering a service to Parexel/client, nor can remuneration be provided to a PAG for peer-to-peer meetings with mutual benefit for both parties.

To ensure consistency and equal treatment of patients/care partner/PAGs, a global methodology on FMV has been established when Parexel contract on our own behalf. This must be adapted in each Parexel entity to set the remuneration rates of patients/care partner/PAGs residing in the country of the entity, considering level of expertise, total time invested, and country of residence.

Parexel may also provide financial support for activities with a professional, educational, or scientific purpose supporting the mission of the PAG, including travel and hospitality. Financial support should reflect actual costs anticipated in connection with the concerned activity. All travel-related expenses shall be reasonable and strictly limited to the purpose of the activity. Hospitality in connection with events shall be limited to travel, meals, accommodation and registration fees, and activities should take place in the country/region where most participants are resident. Approval of financial support must be obtained in advance from the Global Compliance Department and Patient Partnerships Team.

The ToV) including any non-monetary ToV, must be detailed in a contract between Parexel/client and the patient/care partner/PAG. A non-monetary ToV by Parexel/client may include providing in-kind services such as, medical writing, technical support or assisting with logistics in connection with an event.

Payments to care partners

- If a care partner is acting in the capacity as an advisor to Parexel (similar to a patient advisor), Parexel will provide compensation in line with the patient advisor FMV rates

- If a care partner is acting in a support capacity to a Parexel contracted patient advisor, Parexel will cover the expenses for the attendance of the care partner (to the same level as the patient advisor they are accompanying) but no compensation payment will be provided to care partners.

Reimbursement for market research or patient insights activities

- For patients and members of the public participating in market research or patient insights, reimbursement is considered a token of appreciation, rather than a professional fee. In these cases, Parexel will keep reimbursement to a minimum and proportionate to the amount of the patient's time and nature of the task (source: British Healthcare Business Intelligence Association (BHBIA) Legal and Ethical Guidelines for Healthcare Market Research).

Note: Please refer to the guidance information on Interactions with Patients and Patient Groups as mentioned in the Related Document Section.

5.3 Fee-for-Service Arrangements for members of the public

On occasions, Parexel may invite members of the public to participate in a Parexel event. If these individuals are not sharing their lived experience of a medical condition, they would not be classified as a patient advocate. In these cases, reimbursement as a token of appreciation, is recommended rather than a professional fee. For example, in the form of a gift card. In these cases, Parexel will keep reimbursement to a minimum and proportionate to the amount of the patient's time and nature of the task.

Reach out to Compliance@parexel.com in advance of the provision of any vouchers/gift cards to obtain pre-approval.

6. Engaging and contracting with PAGs

6.1 Screening and Compliance Process

Before you consider working with a PAG you must contact the Parexel Patient Partnerships Team (+pagengagementservices@parexel.com).

PAG screening and contracting activities will be undertaken by the Parexel Patient Partnerships Team following a defined screening and compliance process.

It is prohibited for other Parexel colleagues to engage in discussions with PAGs regarding sponsorship and partnership opportunities without first informing the Parexel Patient Partnerships team.

Once a PAG has undergone the Parexel screening and compliance process, an engagement plan will be agreed upon with the Parexel Patient Partnerships team and a PAG Champion will be identified by them to lead the engagement activities with the PAG (the identified PAG Champion may be from the Parexel Patient Partnerships team or other business functions across Parexel).

The following advisory and consultancy activities may also be initiated with PAGs and their representatives. All interactions with PAGs on behalf of Parexel need to be managed by the Parexel Patient Partnerships team.

- Sponsorships and contribution to costs related to events
- Donations or Grants
- Qualitative or quantitative research activities
- Partnerships
- Education
- Any interaction that involves a ToV, including non-monetary support, where Parexel provides benefit-in-kind, such as advice or consultancy or administrative services like graphic design, printing, etc.

6.2 Country Specific Requirements

United Kingdom (UK)

When working for clients in the UK there are specific requirements to comply with the UK Association of the British Pharmaceutical Industry (ABPI) code (refer to clause 27 'Relationships with Patient Organisations' of the ABPI Patient Sourcebook). These include a requirement to 'certify' certain PAG contracts/agreements and PAG/patient facing materials including Social Media posts by a signatory person acting on behalf of the company and these certifications must be reviewed and re-certified every 2 years. This person must be a

registered medical practitioner or pharmacist registered in the UK, appropriately trained in the ABPI code, and their name notified in advance to the local authorities. Please seek additional local advice from the client before proceeding with such activities.

Note: UK based employees or those working for UK clients or any activities in UK must never interact with Social Media posts related to clients or client products and therapies.

European Union (EU) countries

Under local EU country codes (which are generally in alignment with the principles of the EFPIA code) or legislation, some countries have a requirement for advance approval of certain PAG contracts/agreements and PAG/patient-facing materials by a 'responsible' and appropriately qualified person acting on behalf of the client. Seek local advice from the client on local laws and codes before proceeding.

6.3 Payment of Invoices and Expenses

- Payment of invoices and expenses to PAGs will be managed by the Parexel Patient Partnerships Team.
- Payment terms should be sensitive to the patient's economic circumstances and pay expenses as soon as possible. Where possible, transport and accommodation should be arranged and paid for upfront by Parexel.

7. Compliance and Legal

7.1 Contractual Framework

Note: Please refer to the guidance information on Interactions with Patients and Patient Groups as mentioned in the Related Document Section.

When Parexel contracts on behalf of clients the agreement must be transparent and include the client's name.

7.2 Potential Conflicts of Interest

All patient engagement activities should be based on a Declaration of Interest, provided by all partners, to identify potentially competing areas that could lead to a conflict of interest in their collaboration. Declaring an interest does not necessarily imply the existence of any conflict, nor should it automatically disqualify a person from participating in the activities. Any potential conflict of interest shall be reviewed by the Compliance team at Compliance@parexel.com.

7.3 Transparency Regarding Reimbursement

Parexel should be prepared to disclose the payment of compensation and expenses relating to accommodation and travel incurred by patients/PAGs during their interactions with us. Our disclosure of expense payments for patients/PAGs includes both out-of-pocket expenses reimbursed to patient groups for their representatives, and expenses paid in advance, it also includes non-monetary benefits-in-kind.

We are always mindful of the potential to create an over-dependency on any funding we provide. Thus, we should be prepared to report the percentage of each PAG's revenue that our contribution covers.

Client costs: Clients are also required (under local laws or codes of practice) to track payments or support (monetary & non-monetary) given to patients (e.g., UK ABPI) and PAGs (UK, European (EU), etc.) and to publish them annually (for example: UK ABPI). To assist Parexel consolidation of client reports, ensure that all such pass-through costs comply with the client requirements and are clearly denoted as **PAG payments** or **patient advisor payments.**

7.4 Events, Meals, Travel, Hospitality and Gifts

Parexel may provide financial support for meetings with PAGs provided that the primary purpose of the meeting is professional, educational, and scientific in nature, or otherwise supports the mission of the PAGs. The venue and location must be appropriate and conducive to informational communication. In addition, any meals or refreshments provided by Parexel must be modest as judged by local standards and should be approved in advance by the Patient Partnerships Team and Global Compliance Department.

There are legitimate reasons to provide modest meals, hospitality, or travel to patients/care partner/PAG representatives, either on behalf of Parexel or a Parexel client. The following guidelines apply.

Business Meals

- Meals must be reasonable and modest by local standards and consistent with local laws.

- Meals are directly related to a legitimate business activity
- Meals must only be arranged on an occasional basis as part of a bona fide exchange of scientific, educational, or business information.
- The meal must take place at a time, venue, and manner conducive to conducting business or sharing of business, scientific or educational information.
- The cost of the venue is reasonable, lawful, and consistent with ethical business practices.
- The venue itself is appropriate and not extravagant or renowned for its entertainment facilities.
- The Parexel host and recipient must both be present at the business meal.
- If alcohol is consumed, it should be consumed in moderation and is included within the meal limits; and when allowed with the PAGs own policies.
- For client-sponsored meetings, it must be permitted by the client's policies and any required approval must be documented in advance.
- Documentation of all expenses must include the name and address of the recipient, the name and address of the PAG, the details of the expense incurred including all receipts, and the purpose or reason for the expenditure.

Travel/Hospitality

Parexel and clients may only pay for travel and accommodation costs incurred by patient/care partner/PAGs in connection with legitimate services consistent with local laws and as defined below:

- May pay only for reasonable travel and accommodation costs incurred by an attendee. Such costs may be covered only where there are valid reasons to support the need for out-of-town travel. Travel for patients must consider the health status and accessibility requirements of the patient.
- Meetings or event should be held in a location convenient to most attendees. The geographic location selected should not become the main attraction of the event.
- If travel is to be covered by Parexel or the client, the expectation would be economy travel, but when a flight is more than six (6) hours duration business class may be acceptable, or under other special circumstances including the health status of patients. Patients may be accompanied by a care partner, where necessary.
- Written documentation clearly stating the purpose of the meeting, names and roles of attendees, location, date, agenda and including meeting sign-in sheets must be maintained. If required, review and pre-authorization by responsible management including SME with knowledge of local rules, must be documented.
- Meeting planning should consider the specific health and accessibility needs of the patient. For example
    - Virtual attendance versus face to face
    - Total meeting duration and number/frequency and duration of breaks
    - Technology accessibility considerations

Gifts to Patients

- Gifts, donations, and grants for a personal benefit are prohibited. However, vouchers of nominal value may be provided as remuneration in market research, or patient insights (or similar) setting, for the participating patient/care partner/members of the public, if allowed by local regulations. Contact Compliance@parexel.com in advance of the provision of any vouchers/gift cards to obtain pre-approval. Clients must approve the use and value of gift vouchers for client-projects.
- Client sponsored interactions: Client approved, educational items or items related to the treatment of a patient which must be of nominal value may be provided if they meet the requirements of national or regional regulations (including their perceived value and their actual purpose and relevance). Reach out to the local SME or Compliance@parexel.com.

8. Further Information

Parexel employees may ask questions regarding engagement with PAGs to the Parexel Patient Partnerships mailbox +pagengagementservices@parexel.com

Queries regarding this guidance may be submitted to the Global Compliance Department at Compliance@parexel.com

9. Referenced Documents

Document Number	Document Title
CP 820	Gift and Hospitality Policy
SOP-SRD-WW-001	SOP-SRD-WW-001 Authoring of Scientific and Regulatory Documents

***Note**: The CDA and contract templates are held and managed by the Parexel Patient Partnerships team and can be requested directly from them:*

CDA template for PAGs

Contract service agreement template for PAGs

Contract service agreement template for Patient Advisors

Guiding Principles of the Parexel Patient Community

10. Related Documents

- MI-GI-PSE-WW-001 Guideline on Interactions with Patients and Patient Groups for Parexel's Internal FMV rates
- ABPI Working with patients and patient organisations - 2022 sourcebook for industry, https://www.abpi.org.uk/partnerships/working-with-patient-organisations/working-with-patients-and-patient-organisations-2022-sourcebook-for-industry/payment/, accessed November 2022
- BHBIA Legal and Ethical Guidelines for Healthcare Market Research (https://www.bhbia.org.uk/guidelines-and-legislation/legal-and-ethical-guidelines, Quick Guide: Guidelines for Patient Research, February 2022)
- PARADIGM (Patients Active in Research in Improvements and Dialogues for an Improved Generation of Medicines) https://imi-paradigm.eu/petoolbox/
- EFPIA guide. 'Working together with patients. Principles for remunerating Patients, Patient Organisation Representatives & Care partner for work undertaken with the Pharmaceutical Industry.' June 2019 https://www.efpia.eu/
- EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations
- EFPIA Working Together with Patient Groups – September 2017
- PhRMA Principles on Interactions with Patient Organizations (accessed January 2023, https://phrma.org/patient-support/PhRMA-Principles-on-Interactions-with-Patient-Organizations)
- EUPATI Guidance for Patient Involvement in Medicines Research and Development (R&D); Guidance for Pharmaceutical Industry-Led Medicines R&D - https://eupati.eu
- FMV guidance National Health Council (USA) https://nationalhealthcouncil.org/fair-market-value-calculator/

11. Revision History

Policy Version:	Version 01	**Effective Date:**	10 May 2023
Policy Owner:	Nichola Gokool	**Replaces Document:**	New document
Active Countries/Region/Unit:	Worldwide	**Responsible Unit:**	PSE
Summary of Change:			
New policy.			
Associated Documents:			

New	None
Updated (Changes made)	None
Retracted (Removed)	None
Obsolete (Replaced)	None

12. 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

13. Storage

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

14. Signatures

Policy Owner Delegate/Subject Matter Expert	Signatory
	Julie Shutt Patient Networks Leader, Patient Recruitment Services

Authorization by Policy Owner	Signatory
	Nichola Gokool Senior Director, Patient Partnerships

PAREXEL International Electronic Signature Page

This page is the manifestation of the electronic signature(s) used in compliance with PAREXEL International's electronic signature policies and procedures and in compliance with applicable regulations.

UserName: Shutt, Julie (shuttj)
Title: Patient Networks Leader, GSS
Date: Tuesday, 09 May 2023, 02:37 PM GMT Standard Time
Meaning: Document content approved.
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UserName: Gokool, Nichola (gokooln)
Title: Senior Director, Customer Strategy, GSS
Date: Wednesday, 10 May 2023, 06:29 AM GMT Standard Time
Meaning: Document content authorized.
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