EphMRA

CODE OF CONDUCT 2020

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Includes:
Australia, Brazil, Canada, Denmark, Finland, France, Germany, Greece, Italy, Japan, Mexico, Netherlands, Norway, Poland, Russia, South Korea, Spain, Sweden, Turkey, UK, USA

CODE OF CONDUCT 2020

Contents

PRINCIPLES OF THE CODE OF CONDUCT

There are twelve guiding principles that underpin the Code of Conduct. These principles are the foundation stones upon which the specific guidelines are built. They are as follows:

I Market Research subjects MUST be able to provide voluntary, informed consent to data collection and use, based upon a clear understanding of the purpose of the data collection and the use(s) to which the data will be put.

II The rights of Market Research subjects MUST be observed, including rights to confidentiality, anonymity and the right to withdraw at any stage.

III Market Research MUST be kept separate from any form of promotion or selling, it MUST NOT be a vehicle for disguised promotion.

IV Market Research subjects MUST be treated fairly and reasonably, with care and courtesy.

V Market Research subjects MUST be protected for the duration of the study – not harmed, exposed, disadvantaged or made to feel uncomfortable in any way. Confidence in Market Research MUST NOT be abused.

VI Data collection MUST be adequate, relevant and limited to the purpose (s) for which it is processed. Researchers MUST be transparent about the personal data they plan to collect, the reason(s) it is being collected and who it will be shared with.

VII Data MUST be processed fairly and lawfully, and only used for the specific and lawful purposes for which it was obtained. Personal data must be accurate and up to date. It must be processed in accordance with the rights of individuals within national and international data protection and privacy legislation.

VIII There MUST be no unauthorised or unlawful processing, loss, destruction or damage to personal data. You must take appropriate technical and organisational measures to keep data safe.

IX Data can only be transferred, to a third party or overseas, when adequately protected.

X Personal data MUST NOT be kept beyond the time required to fulfil the immediate purposes of the study.

XI Researchers MUST behave ethically; they MUST NOT undermine or damage the reputation of healthcare Market Research. They MUST NOT disparage or appear to disparage competing companies or products.

XII Researchers MUST conduct Market Research accurately, transparently, objectively and of appropriate quality.

Purpose

The Code of Conduct provides comprehensive and up–to–date key ethical and legal guidance to support EphMRA members when they carry out multi–country, primary and secondary healthcare Market Research. This includes ad hoc and syndicated work upon pharmaceutical drugs, biologics, medical devices and diagnostics (available with or without prescription). Within the Code the umbrella term 'products' refers to drugs, biologics, devices and diagnostics unless specified otherwise e.g. medicinal products refer only to drugs and biologics.

It is an industry–sponsored code that aims to define and safeguard the rights of Market Research subjects, protecting data integrity alongside the rights of Market Research subjects.

Geographic Scope

The Code provides international guidelines, although its development has focused upon – Australia, Brazil, Canada, Denmark, Finland, France, Germany, Greece, Italy, Japan, Mexico, Netherlands, Norway, Poland, Russia, South Korea, Spain, Sweden, Turkey, UK and the USA.

It offers international guidelines rather than country specific detail however key inter–country differences are highlighted where they exist.

EphMRA Members' Code Responsibilities

EphMRA strongly recommends that all members adhere to the Code of Conduct and ensure that all personnel employed or sub–contracted on their Market Research studies understand and agree to abide by the Code.

EphMRA also recommends that contracts include a clause committing all parties engaged in the Market Research study – the commissioning company, the Market Research agency and any sub– contractors – to adhering to the EphMRA Code, including adverse event reporting guidelines.

All Market Research MUST comply with international and national law. This 2020 update incorporates the data protection requirements introduced via the General Data Protection Regulation (GDPR) on 25 May 2018.

Whilst incorporating relevant legislation, neither the Code of Conduct nor EphMRA will be a source of legal advice. The information within EphMRA's Code of Conduct is not intended and should not be construed as or substituted for legal advice. It is provided as a reference for best practice. If legal advice is needed it is should be sought independently.

Relationship with other Codes of Practice

EphMRA's Code of Conduct complements other professional codes of conduct/practice e.g. the ICC/ESOMAR International Code on Market, Opinion and Social Research and Data Analytics. Where appropriate readers are referred to complementary/ additional sources of information. Local codes should be observed.

Australia

The Research Society Code of Professional Behaviour https://researchsociety.com.au/standards/code–of–professional–behaviour

Medicines Australia's Code of Conduct https://medicinesaustralia.com.au/wp–content/uploads/sites/52/2020/01/20200108–PUB–Edition–19–FINAL.pdf

Australian Privacy Principles Guidelines https://www.oaic.gov.au/assets/privacy/app–guidelines/app–guidelines–july–2019.pdf

Brazil

INTERFARMA Code of Conduct https://www.interfarma.org.br/codigo–de–conduta

Canada

Innovative Medicines Canada Code of Ethical Practices came into effect on January 1, 2020 http://innovativemedicines.ca/wp–content/uploads/2019/12/IMC–EthicalPractices–2020–web–lowres–EN.pdf

CRIC Public Opinion Research Standards and Disclosure Requirements https://www.canadianresearchinsightscouncil.ca/standards/por/

Denmark

ENLI GUIDE on market research August 2019 http://www.enli.dk/media/49853/guidance–on–market–research–surveys–2019.pdf

ENLI The Danish Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals http://www.efpia–e4ethics.eu/usd/e4ethics.nsf/_/590CD31101711D36C125806E003BF436/%24File/farma_110024.pdf

Finland

Pharma Industry Finland Code of Ethics – Pharma Industry Finland 2019

https://www.pif.fi/media/tiedostot/pif–code–of–ethics–2019.pdf

France

ASOC Charte De Pratiques Loyales En Matière D'études des Opinions Et Comportements Dans Le Domaine De La Santé

http://www.asocs.info/pratique/generalites/

Dispositions déontologiques professionnelles Applicables aux entreprises du médicament adhérentes du Leem December 2019 https://www.leem.org/sites/default/files/2020-01/20%2001%2013%20-%20DDP%20MAJ%20d%C3%A9c%202019%20-%20nouvelle%20charte%20graphique%20-%20modif%20page%20sommaire%20sans%20modification%20apparente%20vf%20ALLONGEMENT%20DELAI%20MSL.pdf

Germany

Declaration for the Territory of the Federal Republic of Germany concerning the ICC/ ESOMAR International Code on Market, Opinion and Social Research and Data Analytics ("German Declaration") https://www.adm-ev.de/en/standards-guidelines/

Guideline Concerning Recording and Observation of Group Discussions and Qualitative Interviews https://www.adm-ev.de/wp-content/uploads/2018/11/RL01_E_Group-Discussions_2006_%C3%9CBERGANG.pdf

Guideline for Studies in Public Health Service for Purposes of Market and Social Research https://www.adm-ev.de/wp-content/uploads/2018/07/RL-Gesundheitswesen.pdf

Greece

SFEE Code of Practice https://www.sfee.gr/wp-content/uploads/2015/04/triptixo.pdf

Code of Ethics on the Promotion of Prescription-Only Medicinal Products & Disclosure of Transfers of Value by Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations as amended by the General Assembly of SFEE, on 16/3/2017 with effect from 01/06/2017 http://www.efpia-e4ethics.eu/usd/e4ethics.nsf/_/026FBF11C0E71594C125806E0042623D/%24File/CODE_EN-2017.pdf

Italy

ASSIRIM Code of Research https://www.assirm.it/en/code-ethics_kcode_ethics.htm

FARMINDUSTRIA Code of Conduct https://www.farmindustria.it/app/uploads/2017/12/Code-18-gennaio-2019.pdf

Japan

Act on the Protection of Personal Information 2017 subject to the "Every-Three-Year Review"

For the medical sector, the Ministry of Health, Labour and Welfare ('MHLW') has issued the following guidance:

- guidance for the appropriate handling of personal information by medical or care-related service providers (only available in Japanese here);
- guidance concerning safety management of medical information systems (only available in Japanese here);
- ethical guidelines concerning medical research targeting humans (only available in Japanese here);
- ethical guidelines concerning analysis and research of the human genome and genes (only available in Japanese here);
- guidelines concerning gene therapy clinical research (only available in Japanese here).

Japan Pharmaceutical Manufacturers Association (JPMA) Code of Practice

- http://www.jpma.or.jp/english/
- http://www.jpma.or.jp/english/policies_guidelines/practice.html

Japan Marketing Research Association Code of Conduct and relevant guidelines

- http://www.jmra-net.or.jp/
- http://www.jmra-net.or.jp/rule/

Japan Medical Marketing Research Group and relevant guidelines

- https://www.medi-ken.org/en/index.html

Mexico

Consejo de Ética y Transparencia de la Industria Farmacéutica Codes https://cetifarma.org.mx/codigos/

Netherlands

Dutch innovative pharmaceutical sector Code January 1, 2020 https://publicaties.verenigninginnovatievegeneesmiddelen.nl/wp-content/uploads/sites/1679/2020/01/Code-Engels-DEF.pdf

MOA Healthcare https://www.moaweb.nl/profgroep-healthcare.html

Norway

LMI – The Association of the Pharmaceutical Industry 2019 http://reklameregler.lmi.no/wp-content/uploads/2017/01/Bransjeregler-2019_engelsk-versjon.pdf

Poland

INFARMA Code of Good Practice https://www.infarma.pl/etyka/

Russia

AIPM Code of Practices 2019 http://www.aipm.org/netcat_files/80/124/h_384a9640bbbb5aadd5071d46f9c44303

South Korea

Korea Pharmaceutical Manufacturers Association Code of Practices KPMA http://www.kpbma.or.kr/attach/englishResource/Code_of_Practices(KPMA).pdf

Spain

FARMAINDUSTRIA Código de Buenas Prácticas de la Industria Farmacéutica 2016

https://www.codigofarmaindustria.org/servlet/sarfi/home.html

Sweden

Ethical Rules for the Pharmaceutical Industry in Sweden Revised 16 April 2020, valid from 01 May 2020 https://www.lif.se/globalassets/etik/dokument/ler-english-version-2020-0501-jd-24apr-pdf.pdf

Turkey

AIFD Code of Good Promotional Practice 7th Edition Effective as of January 1st, 2019 https://www.aifd.org.tr/wp-content/uploads/2019/10/AIFD-Code-of-PracticeENG2019.pdf

United Kingdom

Market Research Society 2019 edition of the MRS Code of Conduct (PDF)

BHBIA Legal and Ethical Guidelines for Healthcare Market Research https://www.bhbia.org.uk/guidelines-and-legislation/legal-and-ethical-guidelines

United States of America

CODE OF STANDARDS AND ETHICS FOR MARKETING RESEARCH AND DATA ANALYTICS APRIL 2019 https://www.insightsassociation.org/sites/default/files/misc_files/ia_codeofstandardsethics4.2019.pdf

EUROPE

EFPIA Relationships & codes https://www.efpia.eu/relationships-codes/

DEFINITIONS

Ad hoc Market Research – is designed and paid for by just one company, the research is exclusive to the commissioning company, who own the resulting data.

Agency – any individual, organisation or department, which is responsible for, or acts as, a supplier on all or part of a Market Research project.

Anonymisation – the process of removing, obscuring, aggregating or altering identifiers to prevent the likely identification, using reasonable means, of the individuals to whom the data originally related.

Anonymity has two interpretations:

- Non–disclosure of a client's identity
- Protection of a MR subject's identity

Carer – professionals or unpaid relatives/friends who provide care for those who because of illness or disability require support, this care may be medical and non–medical.

Client – any individual or organisation that commissions (including requesting or subscribing) all or part of a Market Research project.

Confidential Research – research projects for the purposes of Market Research that do not disclose personal details at an identifiable level.

Consent – the freely given and informed agreement by a person to take part in Market Research and the processing of their personal data.

Consultant – any individual or organisation that provides research services. Consultants can also be a sub–contractor in the research relationship.

Data Controller – a person who alone, jointly or in common with others determines the purposes for which and the manner in which any personal data are processed and is responsible for ensuring that the provisions of Data Protection legislation are complied with.

Data Processor – any person (other than an employee of the Data Controller) who processes data on behalf of the Data Controller.

Data subject – any individual whose personal data is used for Market Research.

Digital listening – the process of extracting data from social media data for analysis. This can be automated or done manually.

Harm – means tangible and material harm (such as physical injury or financial loss), intangible or moral harm (such as damage to reputation or goodwill), or excessive intrusion into private life, including unsolicited personally–targeted marketing messages.

Healthcare professional (HCP) – any licensed member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of their professional activities, may administer, prescribe, purchase, recommend or supply a medicine. Non–HCP could include a patient, sufferer, carer, family member or member of the public.

Identity – the identity of a Market Research subject includes, as well as their name and/or address any other information which offers a reasonable chance that they can be identified by any of the recipients of the information.

Interview – any form of contact with a Market Research subject to collect information for Market Research purposes.

Interviewer – the person who collects data from Market Research subjects for Market Research purposes.

Masking – is a technique whereby the original social media data such as comments, photos or videos is altered to a point that it cannot be traced back or attributed to the original user (e.g. using a search engine).

Market Research subject – an individual or organisation that is approached for interview or from which information is collected for the purposes of a Market Research project, whether they are aware of it or not. This term individuals and organisations who that are involved actively or passively and replaces the use of the term Market Research subject and participant.

MROC (Market Research Online Community) – online community created specifically for the purposes of market, social and opinion research. Others include DORC (Dedicated Online Research Community).

Passive social media monitoring – is the extraction of data from social media for analysis, there is no interaction with the contributor. It is also known as digital listening or scraping.

Primary Market Research – generates original data collected to solve the problem in hand, data is collected directly from Market Research subjects. Primary data is derived from new and original research designed to address a specific purpose.

Privacy notice/policy – published summary of an organisation's privacy practices, it describes the ways in which the organisation gathers, uses, discloses and manages a data subject's personal data.

Public Domain – information, which is published and generally accessible or available to the public, content that is not owned or controlled by anyone, intellectual property being not protected under patent or copyright, in Market Research context it refers to information that is freely available, without restriction.

Public Place – one to which the public has free access and where an individual reasonably could expect to be observed and/or overheard by other people (e.g., in a shop or on the street).

Pseudonymisation – pseudonymisation is the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person. (Article 4(5) GDPR).

Record – defined as any brief, proposal, questionnaire, Market Research subject identification, check list, record sheet, audio or audio–visual recording or film, tabulation or computer print–out, EDP disc or other storage medium, formula, diagram, report, etc. in respect of any marketing research project, whether in whole or in part. It covers records produced by the client as well as by the researcher.

- Primary records are the most comprehensive information on which a project is based, including not only original data records but also anything needed to evaluate those records e.g. quality control documents
- Secondary records are any other records about the Market Research subject and the research results

Recruiter – the person who identifies and invites Market Research subjects to take part in a Market Research project.

Researcher – an individual or organisation carrying out, or acting as a consultant on, a Market Research project, including those working in client organisations.

Secondary Market Research – Involves collecting and using data that already exists. This data is then re–used and reanalysed, so it is data already gathered for one use that is then utilised for another purpose.

Special Category Data (previously referred to as Sensitive Personal Data) – defined as personal information covering the racial or ethnic origin of the Market Research subject; their political opinions; religious beliefs of a similar nature; whether they is a member of a trade union; their physical or mental health or condition; sex life; the commission or alleged commission by him/her of an offence or any proceedings for an offence committed and the outcome.

Scraping – is the process of extracting data from social media data for analysis. This can be automated or done manually.

Social media data – refers to the information (photos, comments, etc.) that users generate or share while engaged in or with social media. It often includes personally identifiable data.

Stimulus material – material shown or referred to or read out to a Market Research subject during fieldwork

Sub–Contractor – any individual or organisation that undertakes a part of a research project (such as the fieldwork).

Syndicated Market Research – is shared – both the findings and the costs – by a number of clients, however the data is owned by the Market Research agency.

Transparency – ensuring individuals have a very clear and unambiguous understanding of the purpose(s) for collecting the data and how it will be used.

Walled garden – online service which requires users to register or apply for membership before being permitted to participate. A walled garden can only be accessed after the user has obtained a login and/or password, even if entry is automatic.

1. WHAT CONSTITUTES MARKET RESEARCH

The term 'Market Research' is used throughout the Code but it is recognised that the Market Research function may go under different names in different organisations e.g. consumer/market insight, business/commercial intelligence, marketing/data analytics, customer science. Market Research is used in this Code as an 'umbrella' term that describes the work meeting the definition below.

With the broadening of Market Research options both in terms of new methods e.g. behavioural economics, co–creation, new mediums e.g. mobile devices and new data sources, it is important to be clear that EphMRA's Code is applicable to both traditional and the newer or non–traditional approaches such as digital listening.

Distinguishing Market Research from other purposes

1.1 Market Research, whatever it is called and whatever approach is used, is defined by the following key characteristics[1]:

- the systematic gathering and interpretation of information about individuals, organisations and marketplaces;
- using the information gathering and analytical methods and techniques of the applied social, behavioural and data sciences;
- its purpose is to gain insight or support decision making;
- the identity of Market Research subjects will not be revealed to the user of the information without explicit consent, Market Research has no interest in the individual identity of Market Research subjects;
- no direct action e.g. a sales approach will be taken in relation to individuals or organisations as a result of the Market Research (except following up adverse events when permitted), Market Research is not a commercial communication or a selling opportunity.

Market Research is defined by the objective(s) and the approach, not by the title of the work or those involved in it. Consequently, the EphMRA Code of Conduct includes areas such as digital listening (the use of social media content for Market Research), the use of observational/ethnographic approaches and work carried out online via mobile devices.

Advisory boards may or may not qualify as Market Research depending how they are run. An advisory board is generally a group that provides non–binding strategic advice to the management of an organisation e.g. providing expert advice on new drugs and opportunities. If the advisory board is recruited and operated as Market Research – meeting the definition above – then it is Market Research. However, Ad' boards do not often offer anonymity, may not be systematic in their approach or supported by a basis in the applied social or behavioural sciences and may not be entirely non–promotional.

1.1.1 **In Australia** Market research must be an initiative to collect relevant information to enhance the quality use of medicines and must not be used as a means to promote to and/or reward participants.

Secondary Use of data

1.2 If the secondary use of data includes personal data, its intended use MUST be compatible with the purpose for which the data was originally collected. The intended use must not be specifically excluded within the privacy notice provided at the time of the original data collection.

1.2.1 **In South Korea** personal information may be used for a new purpose or if doing so does not infringe the interests of a data subject and one of the following conditions is satisfied: (i) the data subject consents; (ii) special provisions exist in any other Act; or (iii) where it is obviously necessary for the physical safety and property interests of a data subject or a third person and it is not possible to obtain consent.

1 Based upon the definition of Market Research contained in the ICC/ESOMAR International Code on Market, Opinion and Social Research and Data Analytics 2016

Market Research, Ethics Approval and Non–Interventional Research

1.3 Market Research (as defined above) relating to market or consumer behaviour of the sort that pharmaceutical companies routinely commission, whether involving healthcare professionals, patients, carers or members of the public does not require Clinical Research Ethics Committee or Independent Review Board approval (Institutional Review Board in the USA).

Key regulators have made it clear what distinguishes 'research' that requires ethics approval i.e. clinical/medical research from 'research' that does not i.e. Market Research.

EFPIA Requirements

EFPIA require non–interventional research studies to meet specific criteria that are not required of Market Research:

- The study is conducted for a scientific purpose;
- There is a written protocol;
- The study protocol MUST be approved by, and the study conduct supervised by, the Company's Scientific Service;
- The study results should be analysed and made available within a reasonable period to the Company's Scientific Service and the Healthcare Professionals who participated in the study;
- If the study shows results that are important for the assessment of benefit–risk profile of the medicinal product, the summary report should be immediately forwarded to the relevant Competent Authority;
- Companies publicly disclose the summary details and results of non–interventional studies in a manner consistent with the parallel obligations for clinical trials;
- Companies apply the same requirements (to the extent applicable) to all other types of studies including epidemiological studies, registries and other studies that are retrospective in nature;
- For further details upon the characteristics of non–interventional studies see Article 15, Non–Interventional Studies of Marketed Medicines within EFPIA's Code on the Promotion of Prescription–only Medicines to, and Interactions with, Healthcare Professionals[2].

UK NHS Guidance

The UK National Health Service Health Research Authority (NHS HRA)[3] provides a decision support tool[3] to help determine whether a study should be classified as 'research' or not:

- Are patients randomised to different groups?
- Is there a protocol to be followed?
- Are the results generalisable[4] to the population?

It also provides a leaflet 'Defining research' that is designed to help you decide if a project is research, which normally requires review by a Research Ethics Committee (REC), or whether it is some other activity such as audit, service evaluation or public health surveillance.

UK's Governance arrangements for research ethics committees A harmonised edition published by the Department of Health, of May 2011:

"2.3.14 Healthcare Market Research may be undertaken by professional Market Researchers on behalf of pharmaceutical or medical device companies. Where such research is conducted by professional Market Researchers in accordance with the Legal and Ethical Guidelines issued by the British Healthcare Business Intelligence Association (BHBIA), it does not require REC review except where otherwise required by law".

2 https://www.efpia.eu/media/24302/3a_efpia–hcp–code–2014.pdf

3 http://www.hra.nhs.uk/research–community/before–you–apply/determine–whether–your–study–is–research/

4 Generalisable is defined as the extent to which the findings of a clinical study can be reliably extrapolated from the subjects who participated in the study to a broader patient population and a broader range of clinical settings.

Key Differences

EphMRA provides a detailed overview of the differences between Market Research (MR), non–interventional studies (NIS) and patient support programs (PSP).

Market Research	Non–Interventional Studies (or post marketing authorisation studies)
Commercial focus/purpose (market behaviour and opportunities) – internal focus	Clinical or medical focus/purpose (safety, efficacy or pharmacokinetics) – external focus Epidemiological methods must be used to design the study and analyse the data Must generate scientifically significant evidence Managed by company's scientific/medical service (rather than commercial)
Market Research is carried out for a commercial purpose i.e. to investigate market behaviour and opportunities to inform business decision making, clinical endpoints are not needed for Market Research	Non–interventional research studies involve the collection of "additional data post–authorisation, as it is necessary from a public–health perspective to complement the available data with additional data about the safety and, in certain cases, the efficacy of authorised medicinal products. Such post–authorisation measures (PAMs) may be aimed at collecting data to enable the assessment of the safety or efficacy of medicinal products in the post–approval setting." (EMA definition[5]) Non–interventional research is carried out for a clinical purpose i.e. to assess safety, efficacy or tolerability, its ultimate purposes are to advance science, the treatment of disease, and improve patient outcomes.

Confusion between Market Research and clinical/medical research can arise because they sometimes address the same audience, may use a similar tool – a questionnaire, and can ask similar questions.

Even Market Research that involves the collection of anonymised patient data detailing conditions, symptoms and treatments this does not mean it is non–interventional research. Market Research using anonymised patient record data is analysed in aggregated form to generate information upon market patterns.

5 http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000037.jsp

The distinction between Market Research and non–interventional research applies whether the Market Research involves prospective or retrospective patient data.

The following table distinguishes between the characteristics of Market Research, patient support programs and non–interventional studies.

Differences between Market Research, Patient Support Programs and Non–interventional Studies

	MR	PSP	NIS
Information gathering tool	Y	N	Y
Patient or carer service	N	Y	N
Participants remain anonymous	Y	N	Y / N
Commercial focus/purpose	Y	Y	N
Clinical focus/purpose	N	N	Y
Direct patient benefit	N	Y	N
Promotional tool	N	Y	N
Directly impacts clinical care	N	Y	N
Pooled processing of information generated	Y	N	Y
Participants are generally financially incentivised	Y	N	N
Impacts patient directly and immediately	N	Y	N
Generally, generates scientifically significant information	N	N	Y
Requires clinical research ethics committee approval	N	N	Y
Can be prospective or retrospective	Y	N	Y
Always involves marketed medicinal product	N	Y	Y
Managed by company's scientific service (rather than commercial)	N	Y / N	Y
Generally, includes patient prescribed a company's medicinal product in the usual manner	N	Y	Y
Epidemiological methods must be used to design the study and analyses the data	N	N	Y

Non–Market Research Activities and Purposes

1.4 It is not Market Research when data are collected for any other purpose than that described above (see rule 1.1).

In general, non–research exercises have the following characteristics:

- Anonymity and confidentiality are not guaranteed;
- If the data are collected on an identifiable basis, direct action (such as selling or direct marketing) will or may be taken;
- The exercise aims primarily to encourage people in general or at random to express views, rather than to achieve robust data based on systematically targeting specific sectors of the population or on the whole range of views from a representative sample of the relevant population;
- The exercise promotes the aims or ideals of a client or organisation;
- The exercise promotes the products or services of a client or organisation;

These definitions are based upon the UK's Market Research Society's Regulations for Using Research Techniques for Non–Research Purposes[6] June 2014

1.5 Database building is a non–research purpose. Data Protection legislation prohibits information given within a Market Research exercise being used to build a database unless consent for this was given at recruitment.

Combining Research and Non–Research Activities

1.6 When researchers are fulfilling their role as researchers, they MUST NOT conduct other non–research activities without the prior informed consent of Market Research subjects.

1.6.1 **In Germany** the Market Research industry guidelines state that Market Research may not be combined with non–research activities. Market Research should be clearly separated and distinguished from any other activity.

Disguised Promotion

1.7 The collection of data to directly create sales or influence the Market Research subjects' opinions MUST NOT be presented to Market Research subjects as Market Research, selling MUST NOT be carried out under the guise of Market Research.

1.7.1 Judgement by regulators as to whether a Market Research survey is disguised promotion is likely to be based on the impact of a series of factors, alone or in combination. Researchers must make sure that:

- At recruitment and in the introduction to the Market Research explain clearly what is involved;
- Justifiable business need and Market Research objectives are clearly documented;
- The minimum sample size and an appropriate sample structure is used;
- Appropriate incentives to the time, tasks and types of Market Research subject are given;
- Guide/questionnaire and stimulus design is balanced;
- There is no unnecessary use of company or brand names or over–emphasis upon claims or product messages, particular care should be taken if the names of unlicensed products are to be used;
- The use of stimulus is clearly sign–posted at recruitment and in the introduction to the Market Research;
- Market Research subjects are made aware that the stimulus is non–promotional and for the purposes of the Market Research alone;
- If stimulus refers to a marketed or an unlicensed product this is made clear;
- The number of times the stimulus is shown is limited to the minimum;
- If repeated exposure is required, explain why this is necessary;

6 https://www.mrs.org.uk/pdf/MRS%20Regulations%20for%20Non%20Research%20Purposes.pdf

- Only essential personal data is collected and the necessity for this is explained;
- Market Research is not run alongside a non–research exercise.

Competitive Intelligence

1.8 Market Research MUST NOT be used to obtain confidential information about competing products and companies from Market Research subjects who are bound by confidentiality agreements with those companies.

Client and Agency

1.9 In terms of the EphMRA Code of Conduct the client is the commissioning party and the agency executes the study on their behalf. Generally, but not necessarily the client is a manufacturer of pharmaceuticals, devices or diagnostics and the agency is a Market Research specialist.

1.10 It is recognised that for some studies there may be more than one 'client' (e.g. different offices may be involved) and more than one 'agency' involved (e.g. a coordinating global agencies and local fieldwork suppliers). In which case for the purposes of the EphMRA Code the following definitions apply:

- *Client* – commissioning company head office or regional office or local affiliate/office, these may be pharmaceutical medicine manufacturers, producers of devices, diagnostics or over–the–counter medicines etc.
- *Agency* – full–service Market Research agency, fieldwork agency, independent recruiter, freelance researcher or interviewer – these may be the main contractor or a sub–contractor. Agencies may also include marketing or management consultancies, PR or advertising companies that run Market Research studies.

1.11 All parties involved should be contractually bound in a chain.

E.G. if pharma' company X's HQ has commissioned international full service agency Y to carry out a multi–country Market Research study on their behalf and agency Y has sub–contracted fieldwork to fieldwork agency Z who has in turn sub–contracted recruitment of Market Research subjects to recruiters A, B and C in three different countries – then, it is expected that the full service agency Y will be under contract to company X, the fieldwork agency will be under contract to agency Y, and finally the recruiters A, B and C will be under contract to fieldwork agency Z

1.12 Sub–contractors should be bound by the same legal and ethical requirements as the main contractor.

1.13 Agencies may not transfer Market Research subjects' personal data to the client without the explicit consent of the Market Research subjects.

1.13.1 **In Denmark** when a pharmaceutical company wishes to conduct a market research study, a written agreement must be entered between the pharmaceutical company/consulting agency and the healthcare professional, where the benefits and the basis for any payment are stated.

2. DATA PROTECTION AND PRIVACY

2.1 National and international data protection and privacy requirements MUST be adhered to.

Personal data is any information relating to an identified or identifiable living person, who can be identified directly or indirectly by that data on its own or together with other data. Personal data includes postal codes, cell phone numbers and email addresses as well as full names and postal addresses. Personal data may be a single piece of information or a series of pieces of information including other information or data sets available to the holder, which together would allow identification of an individual or infer their identity.

Sensitive or special category personal data is personal information which identifies a living individual and includes reference to: the racial or ethnic origin of the data subject; their political opinions; their religious beliefs or beliefs of a similar nature; whether he/ she is a member of a trade union; their physical or mental health or condition; their sexual life; the commission or alleged commission by him/ her of an offence; or any proceedings for any offence committed or alleged to have been committed by their and the outcome. The definition of health data has been expanded to include biometric and genetic data.

- **You must obtain explicit consent to process special category personal data.**
- **You must treat special category personal data with greater care than other personal data.**

Personal data includes data in a range of formats – alphabetical, numerical, graphical, photographical or acoustic. It includes information kept on paper, as well as information stored in a computer memory by means of binary code, or on a videotape, for instance. Personal data includes video–streams (relayed live or delayed and non–anonymised recordings). Whether an audio recording is considered personal data may depend on whether the surnames of the individuals are recorded or whether the voice alone could lead to the identification of the individual.

Once all identifiers linking data to a Market Research subject have been removed then it is no longer personal data (it has been irreversibly anonymised) and is not covered by the EU GDPR. Researchers may use a unique identifier (e.g. a serial number) to identify a Market Research subject (a process referred to as pseudonymisation) but the file linking personal data to the unique identifier MUST be stored entirely separately from the anonymised Market Research subject data. If access to the means to reverse the pseudonymised data is available, the data is still classified (under GDPR) as personal data. In addition, researchers must make sure that de–identified data cannot be traced, or an individual's identity inferred by deduction.

2.1.1 **In the USA the definition of personal data** varies widely by regulation. The Federal **Trade Commission** considers information that is linked or reasonably linkable to a specific individual, which could include IP addresses and device identifiers, as personal data.

The California Consumers Protection Act defines personal information as any information that identifies, relates to, describes, is capable of being associated with, or could reasonably be linked, directly or indirectly, with a particular consumer or household. The definition specifically includes contact information, government IDs, biometrics, genetic data, location data, account numbers, education history, purchase history, online and device IDs, and search and browsing history and other online activities, if such information is linked or linkable with a particular consumer or household. Under the law, consumer is broadly defined as any resident of California.

The definition of sensitive personal data varies widely by sector and by type of statute. Generally, personal health data, financial data, credit worthiness data, student data, biometric data, personal information collected online from children under 13, and information that can be used to carry out identity theft or fraud are considered sensitive. For example, state breach notification laws and data security laws generally apply to more sensitive categories of information, such as Social security numbers and other government identifiers, credit card and financial account numbers, health or medical information, insurance ID, online account credentials, digital signatures, and/or biometrics.

2.1.2 **In Japan** *Personal information* is information about a living individual which can identify a specific individual by name, date of birth or other description contained in such information. Personal Information includes information which enables one to identify a specific individual with easy reference to other information. According to the guidelines issued by the PPC, "easy reference to other information" means that a business operator can easily reference other information by a method taken in the ordinary course of business. If a business operator needs to make an inquiry of another business operator to obtain the "other information" and it is difficult for the business operator to do so, such a situation would not be considered an "easy reference to other information". Personal information includes any "Personal Identifier Code". A Personal Identifier Code refers to certain types of data specified under a relevant cabinet order of the APPI and includes biometric data which can identify a specific individual, or data in the form of a certain code uniquely assigned to an individual. Typical examples of such code would be passport numbers or driver's license numbers. Sensitive information includes information about a person's race, creed, social status, medical history, criminal record, any crimes a person has been a victim of, and any other information that might cause the person to be discriminated against.

2.1.3 **In Russia** data subjects are entitled to access their personal data, request specification or the termination of processing and the destruction of incorrect or incomplete personal data as well as data processed in violation of Russian data protection law. Data subjects are entitled to receive information about the categories of personal data processed, the purposes of the processing, the legal grounds for the processing, the terms of the processing, the legal consequences of the processing, the persons having access to personal data and other information related to the processing of their personal data.

2.1.4 **In South Korea** sensitive personal information can be processed ONLY to the extent a law requires it or permits it; or if separate consent has been obtained from the data subject.

2.1.5 **In Australia** personal information means information or an opinion about an identified individual, or an individual who is reasonably identifiable, whether the information or opinion is true or not, and whether the information or opinion is recorded in material form or not. Sensitive information means information or an opinion about: Racial or ethnic origin; Sexual orientation or practices; Health information about an individual; Genetic information about an individual that is not otherwise health information; Biometric information that is to be used for the purpose of automated biometric identification or verification; Biometric templates.

2.1.6 **In Brazil** *Personal Data* is information related to an identified or identifiable natural person. *Sensitive Data* is personal data on racial or ethnic origin, religious belief, political opinion, trade union or religious affiliation, philosophical or political organisation membership, data relating to health or sex life, genetic or biometric data.

Market Research Subjects' Rights to Their Personal Data

2.2 Market Research subjects MUST be provided with a privacy notice which tells them clearly what their rights are. It must include information such as what personal data is collected, how it is used, how it will be managed, how long it will be stored and the conditions under which it will be shared including transferred outside the EU, as well as how to get more information or make a compliant. The privacy notice must be made available by the individual/organisation collecting the personal data and must be honoured by all parties that process the personal data (whether or not they are the originator of the privacy notice).

2.2.1 **In Australia** companies must provide individuals with access to their personal information held by the organisation upon an individual's request. Additionally, individuals have a right to correct inaccurate, out–of–date, and irrelevant personal information held by an organisation.

2.2.2 **In Mexico** data controllers must inform data subjects, prior to collecting their personal data, of the characteristics of the processing. The document must include, at a minimum, the following information: the identity and address of the data controller; the purposes of the processing; the options and means offered by the data controller to the data subject to limit the use or disclosure of his/her data; the means for exercising the rights of access, rectification, cancellation, and objection ('ARCO rights'); the means for exercising the right to revoke consent to the processing; the transfers of data that the data controller intends to make, if any; and the procedure and means by which the data controller will notify the data subject of any changes to the privacy notice. Data controllers need to establish easily accessible means for data subjects to exercise their ARCO rights, as well as to limit the use and disclosure of personal data and to ensure data subjects' right to revoke consent.

2.2.3 **In Russia** Data subjects are entitled to access their personal data, request specification or the termination of processing and the destruction of incorrect or incomplete personal data as well as data processed in violation of Russian data protection law. Data subjects are entitled to receive information about the categories of personal data processed, the purposes of the processing, the legal grounds for the processing, the terms of the processing, the legal consequences of the processing, the persons having access to personal data and other information related to the processing of their personal data.

2.2.4 **In USA** privacy law is a complex patchwork of national privacy laws and regulations that address particular issues or sectors, state laws that further address privacy and security of personal information, and federal and state prohibitions against unfair or deceptive business practices. This Code will focus on the Health Insurance Portability and Accountability Act, members are required to double check state by state guidance (e.g. California Consumers Protection Act).

The Insight Association Code requires researchers to:

- Have a privacy policy that is easily available (including being publicly available if appropriate) and clearly states their data protection and privacy obligations and practices.
- Only share a data subject's PII with any third–party
  - With that data subject's consent; or
  - In limited situations that are in the interest of the data subject or the public. Such limited situations include, but are not limited to adverse event reporting, health and safety, and situations pursuant to required legal process.
- Ensure that all PII collected, received or processed by the researcher or any subcontractor or other service provider is secured and protected against loss, unauthorised access, use, modification, destruction or disclosure by the implementation of information security measures required by applicable laws and regulations.
- Limit data collection to what is necessary for the specific research and analytics purposes.
- Comply with all applicable international, national, state and local laws and regulations, and local codes of conduct with respect to PII and the local variations in the definition and requirements for sensitive data.

2.3 Market research subjects MUST be made aware of their data subject rights:

- The right to be informed
- The right of access
- The right to rectification
- The right to erasure
- The right to restrict processing
- The right to data portability
- The right to object
- Rights in relation to automated decision making and profiling

Processing Personal Data

2.4 Researchers must limit the collection and/or processing of personal data to the minimum required to meet the needs of the Market Research.

2.5 The processing of *personal data includes any operation* or *set of operations performed on personal data*, including, but is not limited to: collecting, recording, organising, storing, adapting or altering, retrieving, consulting, using, disclosing by transmission, disseminating or otherwise making available, aligning or combining, blocking, erasing or destroying, whether automatically or otherwise.

In the EU under GDPR there are six lawful bases for processing personal.

For further explanatory detail please see EphMRA's GDPR guide to 'Legal Grounds for Data Processing', available on the EphMRA website

2.5.1 **In the USA** the HIPAA Privacy Rule is a federal regulation which gives the individual rights over their health information (i.e. name, address, health status and other information that can be linked to an individual) and sets limits upon how this information can be used or disclosed by "covered entities" (primarily health care providers and health insurers). This regulation also now applies directly to "business associates," which are service providers to these covered entities. Unless a use or disclosure is permitted by the HIPAA Privacy Rule, it can only be made subject to an individual's authorisation. There is no restriction upon the use or disclosure of this "protected health information" if it has been de–identified in accordance with the standards set by the Privacy Rule (see 19.3). The US Marketing Research Association's Best Practice Guidelines on HIPAA state that "As a general matter, survey research entities are NOT covered entities under HIPAA, but may be business associates. The HIPAA Privacy Rule applies when a business associate collects, uses or maintains personal health information for a covered entity."

2.5.2 **In Russia** Personal data may be processed by a "data operator" only with prior written notification to the Roskomnadzor. The notification must occur prior to the first processing of personal data. Processing of personal sensitive data and biometric data requires obtaining the prior consent of data subjects. Such consent may be required to be provided in the form of a written hardcopy. Data Localisation Law implies that once personal data is collected, it shall be placed in the database located in Russia, i.e. the primary database so that all mentioned operations on data should be carried out locally. Afterwards, the data can be transferred abroad for further processing, i.e. to the secondary database.

As a general rule, consents by a data subject may be given in any form, but it is the data controller's obligation to provide proof that he has the data subject's consent. Because of this burden of proof, it is important to keep careful records of consents.

2.5.3 **In Mexico** data controllers must obtain explicit and written consent from data subjects in order to process sensitive personal data.

2.5.4 **In Turkey** pursuant to the LPPD, collected personal data must be all of the following:

- Processed fairly and lawfully;
- Accurate and up–to–date;
- Processed for specific, explicit and legitimate purposes;
- Relevant, adequate and not excessive;
- Kept for a term necessary for purposes or for a term prescribed in relevant laws for which the data have been processed;

Further, in principle, personal data cannot be processed without being collected and processed with explicit consent of the data subject.

Pursuant to Article 10 of the LPPD, data controllers or their authorised persons have an obligation to inform data subjects during the collection of the personal data. As part of the collection of data from the data subject the controller is obliged to provide the data subject with the following information:

- Identity of the controller and of its representative, if any;
- Purposes of the processing for which the data is intended;
- Recipients of the data and the reasons for transfer;
- Process of collecting data and the legal grounds;
- Rights of the data subject;

Where the data has not been obtained from the data subject, the controller shall provide the data subject with the above stated information as well as details of the categories of data concerned.

Processing of sensitive personal data without explicit consent of the data subject is generally forbidden, although sensitive data other than health and sexual life data can be processed without explicit consent of data subject if a law / legislation permits such processing. Under the LPPD, data controllers need to take adequate measures required for the processing of sensitive personal data and comply with the decisions and guides of the Personal Data Protection Board designating such adequate measures. See also Personal Data Protection Board Decision dated January 31, 2018, numbered 2018/10 on Adequate Measures to be taken by Data Controllers in Processing the Special Categories of Personal Data.

Health data and sexual life data can only be processed by natural persons who are under an oath of secrecy or by authorities for the purposes of protecting public health, preventive medicine, medical diagnosis, the provision of care and treatment services or planning, and the management and financing of healthcare services.

2.5.5 **In Brazil** the treatment of personal data may only be carried out based on one of the following legal bases:

- With data subject consent;
- To comply with a legal or regulatory obligation by the controller;
- For carrying out studies by research entities, ensuring, whenever possible, the anonymisation of personal data;
- For the execution of a contract or preliminary procedures related to a contract of which the data subject is a party;
- For the regular exercise of rights in judicial, administrative or arbitration procedures;
- For the protection of health, in a procedure carried out by health care, health services or sanitary authority professionals;
- To fulfil the legitimate interests of the controller or a third party, except in the case of prevailing the fundamental rights and freedoms of the data subject.

As for the processing of sensitive personal data, the treatment can only occur when the data subject or her or his legal representative consents specifically and in highlight, for specific purposes; or, without consent, under the following situations:

- As necessary for the controller's compliance with a legal or regulatory obligation;
- Shared data processed as necessary for the execution of public policies provided in laws or regulations by the public administration;
- For carrying out studies by research entities, ensuring, whenever possible, the anonymisation of personal data;
- For the regular exercise of rights, including in a contract or in a judicial, administrative and arbitration procedure;
- Where necessary to for the protection of life or physical safety of the data subject or a third party;
- The protection of health, exclusively, in a procedure performed by health care, health services or sanitary authority professionals, or
- Ensuring the prevention of fraud and the safety of the data subject.

The controller and operator must keep records of the data treatment operations they carry out.

2.5.6 **In Japan** when handling personal information, a business operator must specify to the fullest extent possible the purpose of use of the personal information ('Purpose of Use'). Once a business operator has specified the Purpose of Use, it must not then make any changes to the said purpose which could reasonably be considered to be beyond the scope of what is duly related to the original Purpose of Use. In addition, when handling personal information, a business operator shall not handle the information beyond the scope that is necessary for the achievement of the Purpose of Use without a prior consent of the individual. The Purpose of Use must be made known to the data subjects when personal information is collected or promptly thereafter and this can be made by a public announcement (such as posting the purpose on the business operator's website). When personal information is obtained by way of a written contract or other document (including a record made in an electronic or magnetic format, or any other method not recognisable to human senses), the business operator must expressly state the Purpose of Use prior to the collection.

Naming the client

2.6 In order to meet GDPR requirements, the end client or the commissioning client company must be named in three situations

- If they are a data controller (see section on Recruitment)

or

- If they are the source of personal data e.g., they supply a list of names to be used for sampling (see sections on Use of Sub–contractors, Revealing the Source of a list and Recruitment)

or

- If they receive personal data e.g., they receive non–anonymised audio/video files – live or delayed (see section Information to be Communicated to Market Research subjects when Observed by Client)

These three situations all operate independently.

2.6.1 **In Australia** researchers must disclose the identity of the client unprompted, no later than the end of the collection of information, except where the Member and the client have reasonable grounds to decide that there are genuine research concerns or another compelling reason not to do so (e.g. it may expose one of the parties to legal action). Comment: Where a Member is relying on such an exception to depart from the general rule, they should make a written record of the reasoning behind this decision. Protocols for revealing the client's identity should be agreed in advance and made clear in the instructions to interviewers or recruiters. These should include: whether the client's identity may be revealed; if so, at what point during the project it would be acceptable to reveal it and procedures for dealing with participants' requests for such detail when it has been decided not to reveal it.

Security

2.7 Researchers are responsible for the safe handling, processing, storage and disposal of Market Research and personal contact data.

2.8 Adequate precautions MUST be taken to protect personal data, any special category data and confidential information against unauthorised access. This would include using the appropriate technological and organisational measures to protect data when it is collected, transferred or stored e.g. reliable encryption systems, firewall and user identification and password access.

2.8.1 **In the USA** in addition to the EU GDPR and US HIPAA (Health Insurance Portability and Accountability Act) requirements that personal data be appropriately protected, certain states have legislation requiring specific security safeguards (e.g., Massachusetts) for any organisation in the state or holding data of a state resident, and various regulators (including the Federal Trade Commission and, recently, the Federal Communications Commission), impose broad overall security safeguards subject to enforcement within their jurisdiction.

Storing Agreements about Access to Personal Data

2.9 Researchers should keep copies of e–mails and other documents received from Market Research subjects agreeing to, or restricting, the use of or access to their personal information. Unnecessary duplication of records should be avoided.

Protection of Personal Data when Transferred

2.10 If personal data is to be transferred from one country to another, the data protection requirements of both countries MUST be met.

2.11 The GDPR[7] restricts transfers of personal data outside the EEA unless. Any transfer of personal data from an EEA country to a third country, and any onward transfer, shall take place only if the appropriate safeguards foreseen by the GDPR are in place. These are:

- Countries covered by an "Adequacy Decision"[8] – in 2020 are Andorra, Argentina, Canada (commercial organisations), Faroe Islands, Guernsey, Israel, Isle of Man, Japan, Jersey, New Zealand, Switzerland, Uruguay and the United States of America (limited to the Privacy Shield framework);
- Binding Corporate Rules – these are data protection policies adhered to by companies established in the EU for transfers of personal data outside the EU within a group of undertakings or enterprises, submitted to and approved by the European Commission;
- Standard contractual Clauses – these are clauses that the European Commission deems sufficient safeguards on data protection for the data to be transferred internationally. Available here https://ec.europa.eu/info/law/law–topic/data–protection/international–dimension–data–protection/standard–contractual–clauses–scc_en
- An EDPB/European Commission approved GDPR Code of conduct together with binding and enforceable commitments of the controller or processor in the third country to apply the appropriate safeguards, including as regards data subjects' rights;
- An EDPB/European Commission approved certification mechanism together with binding and enforceable commitments of the receiver outside the EEA;
- Derogations under Article 49 GDPR.

2.12.1 **In Japan** Personal Data (meaning Personal Information stored in a database) may not be disclosed to a third party without the prior consent of the individual, unless an exception applies. The prior consent of the data subject to a transfer of its personal data (including sensitive information) is not required if the transfer is permitted by law; if after the period necessary for the data subject to exercise its opt–out right has expired and has been notified. Under the APPI, in addition to the general requirements for third party transfer, prior consent of data subjects specifying the receiving country is required for transfers to third parties in foreign countries unless the foreign country is white–listed under the enforcement rules of the APPI or the third party receiving Personal Data has established similarly adequate standards for privacy protection as specified in the enforcement rules of the APPI (e.g. EEA Countries).

2.12.2 **In Mexico** where the data controller intends to transfer personal data to domestic or foreign third parties, other than to the data processor, it must provide them with its privacy notice and the processing purposes the data subject consented to. To legally transfer personal data, data transfer agreements must be signed. In addition, all data transfers to third parties, not processors, need to be informed through the privacy notice and consented to by data subjects (unless one of the exceptions to the obligation to obtain consent for the transfer applies). For transferring personal data to data processors, consent from data subjects is not required and it is not necessary to provide information about these transfers in the privacy notice. A data processing agreement should be executed (or data protection clauses included in an agreement with the data processor).

2.12.3 **In Russia** unless authorised by Russian law or international treaties to which Russia is a party, data transfer is only possible if performed on the basis of an agreement concluded between a company transferring data (data controller) and the company receiving it for further processing (other data controller or data processor). Data controllers must ensure that the consent of individuals for the transfer of their data to any third party is executed in accordance with the provisions prescribed by the Law on Personal Data. This also applies to any cross–border transfer, if data is transferred outside Russia.

7 For more information please refer to https://ec.europa.eu/info/law/law–topic/data–protection_en

8 Cases in which the European Commission has decided that the third country, a territory or one or more specified sectors within that third country, or the international organisation in question ensures an adequate level of protection

2.12.4 **In Turkey** the LPPD distinguishes between the transfer of personal data to third parties in Turkey and the transfer of personal data to third countries.

Transfer of personal data to third parties.

In principle, personal data can be transferred to third parties with the explicit consent of the data subject. The conditions and exemptions applied to collection and processing of personal data also apply to the transfer of personal data to third parties.

Transfer of personal data to parties in third countries.

In addition to the conditions and exemptions applied to the transfer of personal data to third parties, one of the following conditions shall exist for transfer of data to parties in third countries:

The country to which personal data will be sent shall have sufficient level of protection.

The data controllers in Turkey and in the target country shall undertake protection in writing and obtain the Personal Data Protection Board's permission.

The Personal Data Protection Board shall declare the countries having adequate level of protection. So far, the Personal Data Protection Board has not announced any country.

However, the Personal Data Protection Board has announced the minimum clauses to be found in the undertakings of data controllers by setting out examples of undertaking where there is not an adequate level of protection in the country where personal data is transferred.

2.12.5 **In South Korea** the data subject must be notified of (i) of the person receiving the personal information; (ii) of the purpose of processing personal information; (iii) of the items of personal information provided; (iv) of the retention period; and (v) that the data subject may refuse to give consent and the consequences of refusal.

2.12.6 **In Australia** personal information may only be disclosed to an organisation outside of Australia where the entity has taken reasonable steps to ensure that the overseas recipient does not breach the APPs in relation to the personal information. The disclosing / transferring entity will generally remain liable for any act(s) done or omissions by that overseas recipient that would, if done by the disclosing organisation in Australia, constitute a breach of the APPs. However, this provision will not apply where any of the following apply: the organisation reasonably believes that the recipient of the information is subject to a law or binding scheme which effectively provides for a level of protection that is at least substantially similar to the Privacy Act, including as to access to mechanisms by the individual to take action to enforce the protections of that law or binding scheme. There can be no reliance on contractual provisions requiring the overseas entity to comply with the APPs to avoid ongoing liability (although it is a step towards ensuring compliance with the 'reasonable steps' requirement). OR The individual consents to the transfer. However, under the Privacy Act the organisation must, prior to receiving consent, expressly inform the individual that if he or she consents to the overseas disclosure of the information the organisation will not be required to take reasonable steps to ensure the overseas recipient does not breach the APPs. OR A 'permitted general situation' applies. OR The disclosure is required or authorised by law or a court/tribunal order.

2.12.7 **In Brazil** the transfer of personal data to other jurisdictions is allowed only subject to compliance with the requirements of the LGPD. Also, prior consent is needed for such transfer, unless:

- The transfer is to countries or international organisations with an adequate level of protection of personal data;
- There are adequate guarantees of compliance with the principles and rights of data subject provided by LGPD, in the form of
    - Specific contractual clauses for a given transfer
    - Standard contractual clauses
    - Global corporate norms, or
    - Regularly issued stamps, certificates and codes of conduct
- The transfer is necessary for international legal cooperation between public intelligence, investigative and prosecutorial agencies;
- The transfer is necessary to protect life or physical safety of the data subject or of third party;
- Authorisation has been provided by the ANPD;
- The transfer is subject to a commitment undertaken through international cooperation;

- The transfer is necessary for the execution of a public policy or legal attribution of public service;
- The transfer is necessary for compliance with a legal or regulatory obligation, execution of a contract or preliminary procedures related to a contract, or the regular exercise of rights in judicial, administrative or arbitration procedures.

Data Protection Impact Assessments

2.13 When preparing a proposal and considering the use of personal data within a Market Research project that falls within the scope of the GDPR a Data Protection Impact Assessment (DPIA) may be needed (or relying on one previously carried for similar work).

DPIAs are only needed in certain circumstances, to find out more about the when DPIAs are needed and how they should be carried out see the BHBIA's guide to Risk and Privacy Impact Assessment available at https://www.bhbia.org.uk/guidelines/gdprupdates.aspx.

CNIL (French data protection authority) released an open source PIA software that helps to carry out data protection impact assessment. Available here https://www.cnil.fr/en/open–source–pia–software–helps–carry–out–data–protection–impact–assesment

2.14 Proposals should include and address key data protection and privacy issues.

3. MARKET RESEARCH TENETS

Informed Consent

3.1 Members MUST ensure that Market Research subjects give their informed consent before information is collected from them.

"cooperation is voluntary and MUST be based on adequate, and not misleading, information about the general purpose and nature of the project when their agreement to participate is being obtained and all such statements shall be honoured." http://www.esomar.org/knowledge–and–standards/codes–and–guidelines.php

- Consent must be a clear, unambiguous, affirmative action.
- Consent should be 'purpose–specific i.e. limited to one specific purpose.

3.1.1 **In Australia** participants must be informed of the Member's privacy policy and that the privacy policy contains information about; i. how the participant may access their identifiable research information being collected and seek to have it de–identified or destroyed, ii. the process of handling complaints of a breach of the Australian Privacy Principles (APPs) and iii. the extent to which the participant's identifiable research information may be disclosed overseas; c) participants are aware of the purpose of the collection; and d) participants are aware of any quality control activity involving re–contact.

3.2 Only personal data that is NECESSARY to the research should be collected

3.2.1 **In Germany** informed consent should be refreshed at regular intervals (e.g. 6 monthly intervals) if long term or longitudinal research is being undertaken.

3.2.2 **In Australia** researchers must only collect sensitive information (whether from the participant or from a third party) where the participant has given consent, and the information is reasonably necessary for a research purpose.

3.3 Information detailing an individual's physical or mental health is classified as 'special category/sensitive personal data' under the GDPR and requires explicit consent for its use. Explicit consent although not clearly defined within the GDPR it is basically a slightly considered to be a higher standard of consent and is necessary for (amongst other things) processing special category (sensitive) of personal data. Explicit consent must be confirmed in a clear and specifically worded statement (oral or written).

3.4 Specific consent is not required for the use of anonymised and non–attributable responses.

3.5 Market Research subjects have the right to withdraw from the interview at any time. This right MUST be made very clear to children.

Confidentiality and anonymity

3.6 It MUST be clear to Market Research subjects that all personal data collected during a Market Research project will be treated confidentially and are purely for the purposes of Market Research unless adverse event reporting is required and separate consent for transfer of personal data for this purpose has been given.

3.7 Market Research subjects' anonymity MUST be strictly preserved. It is important to note that withholding a Market Research subject's name is not necessarily sufficient to protect their anonymity especially when Market Research subjects belong to small high–profile universes.

3.7.1 **In Greece** the data from HCPs referring to patients shall be collected and delivered fully anonymised and in aggregate form.

3.8 **In Denmark**[9] Anonymous market research. It is stated in the Danish Medicines Agency's guide to the Association Order that anonymous market research, in which the study is conducted by a third party/ external agency, and where the pharmaceutical company and the healthcare professional do not know each other's identity, are not considered an association. It is a requirement that the anonymity between the actual pharmaceutical company and the physician, dentist or pharmacist, respectively, is maintained before, during and after the survey (double blinded studies). It is ENLI's opinion that the fact that a market study only deals with one medicine, where the healthcare professional may be able to figure out who the sender company is, does not necessarily mean that anonymity is considered broken. In such cases, one will not normally have to apply for permission to participate in an interview. However, it is crucial here that the anonymity between the contributing healthcare professional and the actual pharmaceutical company is maintained both before and after the study has been carried out. Researchers MUST ensure that information identifying the Market Research subject (e.g. recruitment questionnaires, attendance lists) is not passed to the client without the Market Research subject's consent.

3.8.1 **In Germany** data that are collected from natural or legal persons, through questioning, observation, recording or by other means, may only be passed on or made available to the client or to other third parties (including internal departments) in a form that does not permit the participants in the study to be recognised or identified (requirement of anonymisation). Accordingly, the data collected may only be used in an anonymised or pseudonymised form. The requirement of anonymisation shall apply irrespective of whether, from the point of view of data privacy legislation, the personal data are collected in the context of a research agency acting as the responsible data controller and the data processor simultaneously or acting as a commissioned data processor only. The collected data may only be passed on or made available in a personalised form between private–sector and public–sector research agencies and research institutions, and only for scientific purposes. This must be agreed on beforehand by contract between the research agencies or research institutions involved. The persons concerned must be informed, considering methodological aspects, about the transmission, provision and use of the personal data concerning them and must consent to this. The data collected and the address data must be separated from one another as soon as possible and the latter deleted. In the case of one–off studies, the data must be deleted as soon as the quality controls for the data collection and, if applicable, the data check have been completed. In the case of follow–up or repeat studies, the address data must be kept separate from the data collected until the end of the entire investigation.

3.8.2 **In Spain** laboratories may only access the identity of the participants in order to supervise and control the quality of the study. For this purpose, access to these data will be temporary for the duration of the quality control activities and there will be no data record of the participants in possession of the laboratory.

3.9 Agencies must not identify the client or any confidential client data without the client's consent except if there is a legal obligation to do so.

9 http://www.enli.dk/media/49853/guidance–on–market–research–surveys–2019.pdf

Waiving Right to Confidentiality

3.10 The Market Research subject's right to confidentiality can be waived by the Market Research subject if specific consent has been sought and granted providing Market Research subjects have been made aware of:

- To whom they will be identified;
- What will happen to the information they give;
- What, if anything, will happen to them as a result of this waiver.

3.10.1 **In Germany** the requirement of anonymisation cannot be overturned by the person concerned agreeing to the data being passed on, supplied or used in a personalised form. In view of the precedence of anonymisation, it is not permissible to obtain such consent in the context of market, opinion and social research. Even when participants in a study explicitly request that the data concerning him or her should be passed on or made available to the client and other third parties (including internal departments) in a personalised form (as well), this request must not be complied with. In this case, participants may only be given an address to contact so that they can approach themselves the client or another third party. In order for this approach to be permissible, it is essential that participants spontaneously and of their own volition request the collected data to be passed on or made available in a personalised form, without the research agency /research institution being involved in this in any way and without its pointing out the possibility of the collected data being passed on or made available in a personalised form.

3.10.2 **In Australia** researchers must obtain consent if they intend to disclose participants' identifiable research information. They must inform participants to whom the information will be supplied and the purpose for which it will be used. Researchers must inform participants at the beginning of the project whether the project is being conducted on an anonymous or identifiable basis and: a) if anonymous, participants' anonymity must be strictly preserved. b) If identifiable, participants must be informed at this stage of the purpose and the recipient of the identifiable research information, unless there are methodological reasons not to do so at this point. Researchers must inform participants of the purpose and recipient again at the end of the collection of information and ask them to reconfirm their consent for disclosure.

Separating Personal and Research Data

3.10.3 **In Germany** Market Research industry guidelines state that personal data MUST be separated from interview data immediately by the research agency, after this the only link allowed between the two is a common code number. The address data – name, postal address, telephone number, and email address – MUST be destroyed at the earliest possible time i.e. once quality control checks have been completed. Personal data cannot under any circumstances be passed to a client, there are no exceptions or waivers allowed. *ADM Key Problems in the Data Protection Laws and Professional Laws for Scientific Survey Research Aug 2009.*[10]

Patient Confidentiality

3.11 Physicians have a duty of confidentiality towards their patients. Information about a patient may be obtained for Market Research from patient records without patient authorisation only if these data are fully anonymised.

3.11.1 **In the USA** only if they meet the de–identified criteria within HIPAA (see 19.3 or www.hhs.gov/ocr/privacy/index.html Aug 2009) or as permitted by the HIPAA Privacy Rule provisions related to research or a "limited data set" or if the patient has given explicit authorisation.

10 http://www.adm–ev.de/fileadmin/user_upload/PDFS/Kernprobleme_E.pdf

4. KEY RESEARCH STAGES – BEFORE FIELDWORK

Approval and Registration of Proposals Prior to Fieldwork

4.1 Researchers MUST inform clients if any of the work to be carried out for them is to be combined or syndicated with work for other clients (any other clients do not need to be named and MUST not be named without their permission).

4.1.1 **In Spain**[11] Market research studies must meet the following requirements:

I. Ignorance of the identity of the people participating in the study. The pharmaceutical laboratory will not have the possibility of knowing, before, during or after its realisation, the identity of the people who participated in the study.

II. Anonymous nature of the information collected. The pharmaceutical laboratory will not have the possibility of associating each of the study participants by name with the data or opinions obtained.

III. Aggregate treatment of the responses or data obtained.

IV. Proportionality between the universe and the sample. Quantitative market research studies pursue a level of representativeness of the universe. When parameters other than those generally accepted in market research are used to calculate the sample size (simple random sample, 5% margin of error, 95% confidence level and 50% heterogeneity level), prior authorisation will be required. of the Deontological Supervision Unit.

V. The person participating in the study is unaware and does not have the opportunity to link its performance with a pharmaceutical company or with a specific product. Therefore, the pharmaceutical laboratory sales network cannot play any role in the development and execution of the study.

The results of the study and the data obtained will not be publicised or used in promotional materials.

Any exception to these requirements must have the prior approval of the Deontological Supervision Unit. In particular, requirements i, ii and v are developed in the complementary standards in the case of product–related market research studies.

Additionally, in order to guarantee that market studies do not imply an induction to prescription, or may contain an incentive prohibited by the Code, pharmaceutical companies undertake to:

- Communicate them prior to their initiation in accordance with the provisions of Title II Regulations of the Code Control Bodies;
- Ensure that the study does not modify the doctor's prescription or pharmacist's dispensing habits;
- Have a written protocol in which the objectives, the methodology, the expected results and their use are clearly established. In this sense, written agreements will be formalised with the professionals and / or entities with which the studies will be carried out, on the one hand, and the company sponsoring the study, on the other, specifying the nature of the services to be provided, the conditions of participation and remuneration of professionals, etc;
- The remuneration of the participating professionals must obey market criteria and be in accordance with the time spent, the work performed and the responsibilities assumed, and must be properly formalised. The remuneration must be monetary. Exceptionally and with prior authorisation from the Unit, remuneration in kind may be delivered;
- Guarantee that the study does not constitute an incentive for the recommendation, prescription, purchase, supply, sale or administration of medications;
- Be approved, prior to its completion, by the scientific service of the laboratory or by the internal supervisor.

These requirements will be applicable regardless of the methodologies, sources or techniques applied for their realisation, for example: survey method, observation, experimental designs, ethnographic techniques, expert groups, qualitative techniques, etc.

11 For full details please see: http://www.farmaindustria.es/Farma_Public_ING/Codigo/codeofsanitaryprofessionals/index.htm

4.1.2 **In Finland** Market research must not focus on a medicinal product which has not obtained the marketing authorisation. Market research must not have an impact on the treatment of individual patients. The market research projects must be limited in their extent, such as one–off telephone interviews or mail, email or web–based questionnaire studies. The opinion of the healthcare professionals must not be repeatedly probed, considering both the frequency of the contacts in general as well as the number of contacts related to individual surveys.

4.1.3 **In Russia** the following requirements should be observed while engaging healthcare professionals to provide services: there should be a written contract describing the substance of the services to be rendered and the terms of payment for these services; compensation for the services should be reasonable and consistent with their fair market value; there should be a reasonable need for the services; there should be a direct connection between the criteria used to select the healthcare professionals to render services and the purpose to be achieved when these services are rendered; the number of the healthcare professionals engaged to render services should correspond to the number actually needed to achieve the relevant purpose; the existence of the services contract should not directly or indirectly oblige the healthcare professional to recommend or prescribe any pharmaceutical product.

Marketing studies conducted directly by pharmaceutical companies or by pharmaceutical companies with the involvement of marketing agencies are only possible provided that applicable legislation is complied with. Neither the pharmaceutical companies nor the agencies engaged in such cases may pay any compensation to any healthcare professionals for their participation in the marketing study. Exceptions may include cases where marketing studies require specialist scientific knowledge and substantial work inputs on the part of a healthcare professional provided that: (1) marketing studies are conducted with the involvement of independent agencies; (2) the healthcare professional is not informed on, and it is unclear from the materials of the study, which pharmaceutical company has ordered / sponsored the study; and (3) the pharmaceutical company is not involved in the selection of the persons to take part in the study and is unaware of which healthcare professionals will be involved in the marketing study.

Use of Sub–Contractors

4.2 Clients should be informed if any part of the study is to be sub–contracted outside of the agency. If requested the identity of the sub–contractor should be provided.

4.2.1 **In Canada**, this is mandatory for MRIA members. If a sub–contractor is employed at short notice after the study has started the client should be informed as soon as practical.

Preparing the sample

Sample Size

4.3 The size of the sample should be appropriate to meet the Market Research objectives. If the sample size is unnecessarily large, the Market Research may be considered a promotional vehicle.

4.3.1 **In Norway** the number of respondents must not exceed the number necessary to ensure a good result.

4.3.2 **In Sweden** a request for participation in market research may only be sent by e–mail or post, unless otherwise agreed in the particular case.

Over–Researching Market Research subjects

4.4 Researchers should manage and monitor the frequency with which potential Market Research subjects participate in Market Research and try to avoid over–researching individuals.

4.4.1 **In Greece** Market Research shall be a snapshot, even if it refers to the past or future intentions, always to random/representative sample of population

4.4.2 **In Australia** where a Researcher discloses identifiable research information to a client for the purpose of regulating frequency of research–related contact with the individual, they must ensure: a) only that part of the information considered necessary for the purpose is disclosed; b) if the purpose could be achieved using de–identified data, it is de–identified prior to disclosure;

c) the information being disclosed relates to the individual's research status and cannot be linked to any research data; and d) the client has agreed to use the individual's research status only for the purpose of regulating frequency of contact with the individual.

Drawing a Sample from a List

4.5 Lists that are drawn from sources readily available within the public domain do not generally require the consent of the individuals listed to have their personal details held (all of the data MUST be drawn from the public domain). However, you MUST always have a lawful basis for processing personal data, whether the data is readily available in the public domain or not.

So if for instance a list of healthcare professionals (HCPs) was drawn up from health centre websites that listed the HCPs working there, this would not necessarily require the HCPs prior consent if a legitimate interests assessment made clear that it was in the data controller's legitimate interests to process data in this way.

If a list containing personal data that is not in the public domain e.g. a list of detailed physicians was passed to an agency to allow them to draw a sample from it, as long as the agency is contractually linked to the client company and the physicians had given consent for their details to be used for Market Research then this does not require the consent of the listed individuals. Legitimate interests or public interests could be an alternative lawful basis.

4.6 The list holder should inform the supplier of the legal basis for passing on their list.

4.7 If, however, local law/regulations demand that the explicit consent of those on the list is required before their personal details are passed on as in Italy, this MUST be complied with.

4.7.1 **In Italy**, data that is used that is not publicly available should be 'certifiable' – those that hold the data MUST have the consent of the individual and evidence of how they obtained the data. It is also strongly recommended by EphMRA that the responsibilities of list suppliers are made explicit and agreed to in writing within some form of project agreement, such as the contract.

Anonymity of Market Research subjects drawn from Lists

4.8 The client company MUST NOT be informed of the identity of Market Research participants, i.e. who on the list was interviewed.

Do Not Contact Status

4.9 Market Research subjects that have chosen to opt–out of or not be contacted for Market Research must be excluded.

Revealing the Source of a List

4.10 When lists of named individuals are used for sample selection, the source of the list should be revealed to potential Market Research subjects. Under GDPR, the source of the list MUST be named. If providing the name of source of the personal data would impact the integrity of the Market Research it may be withheld until the end of the interview, but Market Research subjects must be made aware at recruitment that:

- the client will be named at the end of the interview;
- they can withdraw their consent at any point;
- the justification for this should be documented.

Correcting Listed Information

4.11 You have a responsibility to make sure that any personal data you process is accurate and up to date. Reasonable steps must be taken to correct or erase inaccurate data promptly.

Adding Personal Data to a Database

4.12 Personal data can be added to the database only if you have a lawful basis for this e.g. the Market Research subject consented to at the time of data collection. Market Research subjects MUST also be told why and for what purposes the data will be used, and that under no circumstances will it be released or used for any non–research purpose.

- An entry recording that a particular individual was interviewed or contacted on a given survey, or that they do not wish to be contacted for further research, is permitted if the purpose of the entry is solely to ensure that that individual will not be unnecessarily approached for research at some later date except in Germany.

4.13 The Market Research subject has the right to request the deletion of any or all of their personal data from the database at any time.

Return or Destruction of Client Databases or Market Research Subject Details

4.14 Client databases MUST be returned to the client or destroyed at the end of the project. Market Research subject requests to have their personal data removed from a list or database must be respected.

Recruitment

Screening Questions and Questionnaires

4.15 Screening questions MUST only be used pre–screen potential Market Research subjects for participation in the research, they MUST NOT be used to collect additional data.

4.15.1 **In Greece** medical sales representatives may not be involved in the conduct of market research.

Data Collected at Recruitment

4.16 Data collected at recruitment MUST NOT be used for any purpose other than the purpose for which consent was granted. Seeking consent for other uses retrospectively is not allowed. Consent must be specific to a single purpose.

Physician Recruitment of Patients

4.17 Physicians may act as intermediaries to recruit patients by inviting patients to take part or passing on questionnaires on behalf of the agency, they MUST however:

- Ensure that patients understand that their participation is voluntary
- Not disclose the patient's identity to the agency until the patient has consented to this.

4.18 Reimbursement should not be dependent on the number of patients successfully recruited. Agencies should beware of placing pressure upon patients and try to minimise this e.g. by issuing a written rather than a face to face invitation.

4.19 If the patients reply directly to the agency, which is preferable, the doctor should not be told which patients are going to/have participated.

4.19.1 **In Germany and Brazil**, physicians are only allowed to pass on and return completed questionnaires if there are no means by which to identify the patients detailed (e.g. name or address).

4.19.2 **In the Netherlands**, MOA affiliated researchers MUST make sure that an invitation to a patient to participate in Market Research that is given via a HCP must be in writing (mail or email).

Snowballing – Market Research subject supply of Potential Market Research subjects' names

4.20 When asking people to supply other people's names for the purposes of developing a list from which to draw a sample (a technique commonly referred to as 'snowballing' and used to identify opinion leaders) to meet the obligation to be transparent, the person being recruited MUST be told how their name was obtained. This means for example that when trying to recruit an opinion leader the recruiter MUST tell the doctor that they were suggested by another physician but there is no need to name the source of the nomination.

Recruitment – Information that MUST be communicated

4.21 You must obtain a record of Market Research subjects' agreement/consent to participate in Market Research. This must detail all the key 'terms and conditions' including data protection requirements associated with the Market Research. This agreement/consent must be collected from all Market Research subjects, both HCPs and non–HCPs.

4.21.1 **In Denmark** if a doctor, dentist or pharmacist is associated with a pharmaceutical company, e.g. by participating in a market study, he/she must apply for association with the company at the Danish Medicines Agency prior to participation. The reason for this is that participation in a market survey is regarded as counselling that requires prior permission from the Danish Medicines Agency. The pharmaceutical companies have an obligation to provide information to healthcare professionals and must notify the Danish Medicines Agency of which doctors, dentists and pharmacists are associated with the company. You can read more about the rules of association on the Danish Medicines Agency's website.

4.22 The agreement/consent must[12] include:

- Subject and purpose of the Market Research;
- Methodology and approach;
- Location and duration of fieldwork;
- Date and time of fieldwork;
- Reimbursement offered – both the nature and the rate of remuneration;
- Adverse event and product complaint reporting obligations if appropriate;
- Templates for a standard text are available in Germany[13] and in the UK[14] where non–healthcare professionals MUST be informed that if adverse events are discussed during the research, then the details will be collected and forwarded to the commissioning pharmaceutical company.

4.22.1 **In Mexico**, the privacy disclaimer (aviso de privacidad) has to be provided (in writing or read) to the Market Research subject, or a source for it given (i.e. hyperlink). Market Research subjects must consent to the terms of the privacy disclaimer.

In addition, in order to meet data protection requirements for informed consent, you must tell all Market Research subjects:

- Identity and contact details of the data controller(s);
- Agency or researcher name and contact details – name, telephone number, email address as appropriate;
- Source of their personal data of it didn't come from the data subject, this may require you to name another organisation e.g. the commissioning client company;
- Recipients of their personal data, this will require you to name any other organisation the personal data is being transferred to e.g. the commissioning client company;
- Why you want their data (purpose) and what you will do with it (types of processing activity) including if and how viewing or recording will take place and who will have access to live or recorded information;
- If the data is not obtained directly from the data subject the categories of personal data;
- Their right to withdraw consent at any time;
- Of any automated decision making and its consequences.

12 EFPIA and local pharmaceutical industry associations' requirements

13 http://www.akdae.de/Arzneimittelsicherheit/UAW–Meldung/index.html and http://www.akdae.de/Arzneimittelsicherheit/UAW–Meldung/UAW–Berichtsbogen.pdf

14 http://www.bhbia.org.uk/guidelines/abpiadverseeventguidelines.aspx

4.23 Either in the consent agreement or in an easily accessible privacy notice, Market Research subjects must also be made aware of:

- Legal basis for the data processing and, if appropriate, the legitimate interests of the data controller or third party;
- Details of the data protection officer (if there is one);
- How long their personal data will be stored;
- The existence of each of the data subject's rights and the right to complain to a supervisory authority, their rights include to:
- Ask what data is being held about them
- Ask for the data to be amended or destroyed
    - Object to processing;
    - Ask to move their personal data;
    - Ask to restrict processing;
    - Exercise their rights in relation to automated decision making and profiling;
    - Where the data processing is based and details of any data transfers to countries without adequate data protection.

4.24 EFPIA members and members of EFPIA–affiliated associations MUST[15]

In Market Research carried out face to face document an agreement between agency or client company and the healthcare professional Market Research subject in advance of fieldwork (i.e. at recruitment) for all.

Longitudinal studies and panels MUST also be covered by a written agreement irrespective of methodology.

Single stage Market Research studies conducted online, by telephone or by post that involve only minimal remuneration do not require a written agreement in advance of fieldwork. EFPIA member associations provide guidance on the meaning of minimal.

4.25 Records of the agreement MUST be kept in line with data protection and privacy legislation (as well as primary Market Research records containing personal data) and MUST be destroyed when the purpose of the Market Research study is redundant.

4.25.1 **In Germany** the FSA requires that if the incentive is not 'marginal' (which is defined as over 50 euros) written contracts are required for all forms of Market Research with HCPs.

4.25.2 **In the UK** see the BHBIA Guidelines[16] section 4.3 Disclosure requirements.

4.25.3 **In Greece** when pharmaceutical companies enter into contracts with market research companies, they may agree for a reasonable compensation to be given to Healthcare Professionals, taking under consideration the working time spent by the HCP, which may not in any case exceed two hours.

4.25.4 **In Turkey** companies may receive consultancy support from healthcare professionals. Travel and accommodation costs may be covered if HCPs are traveling to offer these services and remuneration can be made to them on the basis of a written contract. Fees for Services The arrangements which cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria: a) A legitimate need for the referred service and consultancy shall be clearly identified and documented in advance before contacting the consultant, requesting the service and initiating talks with potential consultants. b) A written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services. c) The criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service d) The hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine; e) The criteria used for selecting a consultant shall fulfil the need which has been identified. Persons appointed for selecting consultants shall have the qualification, knowledge and skills to assess whether the relevant healthcare professionals meet these criteria. f) The number of healthcare professionals retained as consultants shall not be greater than the number required for fulfilling the need identified and

15 This ruling is based upon Article 14 of the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code on the Promotion of Prescription–Only Medicines to, and Interactions with, Healthcare Professionals http://transparency.efpia.eu/uploads/Modules/Documents/efpia-hcp-code-2014.pdf

16 http://www.bhbia.org.uk/guidelines/legalandethicalguidelines.aspx and http://www.pmcpa.org.uk/thecode/Pages/default.aspx

achieving the goal. g) The company requesting consultancy shall keep records demonstrating that they have received services offered by consultants and used these in line with their needs. h) The compensation for the consultancy or services must be reasonable and shall reflect the fair market value. The compensation arrangement may include reimbursement of reasonable expenses including travel, meals and accommodation It is not allowed to prepare on–paper agreements to justify any payment to be made to healthcare professionals.

4.25.5 **In Japan** in interactions with healthcare professionals, research companies shall give the highest priority to being of benefit to patients and contributing to the health and welfare of patients. With the goal of contributing to the development of medical and pharmaceutical science and the improvement of public health, research companies' interactions shall focus on the provision of drug information, academic exchange on medical and pharmaceutical science, and support for research. When promoting industry–academia collaboration to further the development of medical and pharmaceutical science, research companies shall make efforts to build relationships of trust with researchers, healthcare professionals, and patient organisations while at the same time avoiding activities that could exert an inappropriate influence upon prescribing decisions. Companies may engage researchers, healthcare professionals, medical institutions, patient organisations, etc., for services such as research, clinical studies, post–marketing surveys, consultant and adviser duties, participation in the planning of meetings, chairing or lecturing at seminars, and training instructor duties, where such participation involves fees such as honoraria. However, when making arrangements for these services, research companies must enter into a written agreement, that fulfils all of the following criteria. (1) A written contract must be agreed which specifies the purpose of the service to be provided and the basis for payment of those services. (2) A legitimate need for the services must be clearly identified in advance. (3) The contractor must be directly related to the identified need and must have the expertise necessary to provide the service. (4) The number of persons to be contracted must be reasonable to meet the specified need. (5) The hiring must not be an inducement to prescribe, purchase, or recommend any specific drug. (6) The compensation for the services is reasonable and reflects the fair value of the services provided.

Naming the data controller, source and recipients of personal data

4.26 If the end client company is a data controller i.e. determining the purposes and means of processing personal data (either alone or jointly with another data controller) their identity must be shared with the data subject.

The European Data Protection Board have suggested that where organisations are jointly determining the purposes and means of processing, they will be considered joint data controllers (in accordance with GDPR Article 26), regardless of whether one controller is only determining the purposes and the other only determining the means. In addition, when in a joint controller scenario, where personal data are collected from the data subject, both controllers must be named (in accordance with the requirements of GDPR Article 13(1)(a)). The EDPB's current view essentially means that within a Market Research context, the end client is likely to be a data controller as the Market Research is taking place for the end client's overall purpose. The second key point to bear in mind is that this is considered the case even if the end client never processes any personal data.

4.27 The source of the personal data and recipients of personal data must also be named at the time that personal data is obtained as part of the Market Research process (whether or not they are data controllers).

4.28 If naming the end client before the interview would undermine the integrity of the work, this may be done at the end of the interview BUT:

- Market Research subjects must be made aware at recruitment that:
  - the client will be named at the end of the interview;
  - they can withdraw their consent at any point.

- If the end client is receiving personal data, they must be named before any transfer takes place.
- The justification for this should be documented.

The requirements for naming the client when observation and recording are taking place are detailed later on.

4.28.1 **In France**, public servants including physicians who work in hospitals MUST have authorisation from their university hospital that they may participate in 'incidental activities' including Market Research. The CNOM may require evidence of this to approve the project. Decree 2011–82 covers public servants and Article L.6152–4 2 of the Code de la Santé Publique (the French public health code) extends this requirement to physicians who work in university hospitals.

For more detail, please see http://www.ephmra.org/Country–News

4.28.2 **In Italy**, the Transparency Act (art. 53 165/2001) requires that:

- Physicians employed by public entities should have the permission of their employers before they participate in Market Research if they are paid an incentive. If no incentive is paid (even if expenses e.g. for travel, are reimbursed), employer permission is not required but the employer should be informed. It is the responsibility of the physician to gain their employer's permission (not the Market Research agency).
- Market Research should take place outside public entities office/clinic hours and not on a public employer's premises unless the premises are used for private practice too.

4.28.3 **In Norway** where market surveys are carried out amongst health authority employees, the exercise should be cleared with the employer. It is the responsibility of the Healthcare Professional to ensure that such clearance exists.

Scheduling of Fieldwork Appointments

4.28.4 **In Italy, Norway and Sweden**, the ADM/BVM, ASSIRM, and LIF respectively, recommend that Market Research appointments with healthcare professionals (HCPs) should be made outside working hours and that those HCPs that are employees are not interviewed on their employer's premises. However, the preferences of the HCPs can be taken into account. **In Italy** this refers to HCPs when employed by the national health service (SSN) only[17].

4.28.5 **In Germany** when making an appointment for participation, the research company carrying out the study or the persons or companies working on its behalf – especially interviewers and field service providers – make appointments outside of the participants' working hours. In addition, the participation of employees or civil servants should take place outside the premises of the employer or employer in which they usually perform their services. The commissioned persons or facilities are to be explicitly advised of these provisions by the research company. However, with regard to the location and the date of participation, the specific wishes of the participants must also be taken into account. In the case of salaried or civil servants, this may include to point out any obligations that may arise from the employment or service contract. This notice must be documented in a suitable manner.

Disclosure

4.29 **EFPIA Disclosure Code**[18] requirements apply to EFPIA and EFPIA affiliated association members and all those that have agreed to adhere to EFPIA or national associations' code of practice.

4.30 The Disclosure Code applies to prescription only medicines and only to over the counter medicines if they are dispensed on prescription. Consequently, pharmaceutical companies will need to disclose payments made to healthcare professionals (HCPs) for a range of activities including participation in Market Research (MR) when (and only when) the pharmaceutical company is aware of the identity of the HCP. These payments are referred to in the Disclosure Code as Transfers of Value (ToV).

4.31 If a sample is to be drawn from a list of HCPs supplied by the pharmaceutical company, the identity of those actually interviewed will not be known and so disclosure is not required. However, if all those on the list are to be interviewed, then the company will be aware of the identity of the HCPs involved in the Market Research and disclosure will be required.

17 Guideline for Studies in Public Health Service for Purposes of Market and Social Research ASSIRM, Directive on the interviews with medical staff for purposes of Market Research and social

18 https://www.efpia.eu/media/25837/efpia–disclosure–code.pdf

4.31.1 **In Australia** any transfer of value to a market research participant should be reasonable for the related services and consistent with upholding the integrity and reputation of the industry. Where a Company is aware of the specific named individual healthcare professionals to participating in market research, payments must be disclosed in transparency reports in accordance with Medicines Australia's Code of Conduct.

When disclosure is required

4.32 For Market Research, disclosure is required when pharmaceutical companies are aware of the identities of those participating in Market Research it has commissioned and ToVs i.e. Market Research –related payments (incentives and expenses) have been made to HCPs. In these cases, the payments made to individual named HCP Market Research subjects MUST be disclosed, whether they've paid them directly or indirectly via an agency. This information will be made publicly available.

4.32.1 **In Greece** the Disclosure of Transfers of Value by Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations applies http://www.efpia–e4ethics.eu/usd/e4ethics.nsf/_/026FBF11C0E71594C125806E0042623D/%24File/CODE_EN–2017.pdf

4.32.2 **In Russia** each pharmaceutical company shall document and disclose transfers of value it makes, directly or indirectly, to or for the benefit of any healthcare professional or healthcare organisation being a recipient. Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year

4.32.3 **In Australia** market research may be undertaken about an approved or unapproved product or unapproved indication. For market research conducted with members of the general public, the product name and/or molecule should not be disclosed. Market research undertaken with patients who have been prescribed a particular prescription medicine may include product–specific questions. Market research studies must be clearly identified as such when the initial approach is made to participants. It must be clear to a participant that the market research is being conducted by or on behalf of a Pharmaceutical Company, but the name of the Pharmaceutical Company need not be disclosed. It is recognised that the disclosure of the name of the Company may bias the research.

4.33 National data protection legislation may require the HCP's consent for their data to be used in this way. If this consent is not given, Market Research payments MUST still be disclosed but on an aggregate basis. So, if HCP Market Research subjects do not consent to their personal data being used for disclosure they may still participate in the Market Research.

When disclosure is not required

4.34 If the HCP's identity is not known to the pharmaceutical company disclosure is not required.

EFPIA have stated that if a HCP's identity becomes known to the company only as a result of an adverse event where reporter contact details are provided, disclosure is not required.

Similarly, if during viewing of non–anonymised fieldwork, a Market Research subject is recognised (and identified) by client company personnel, disclosure may not be required.

4.34.1 **In Turkey** in order to protect the integrity of the research when a market research is conducted, the company name may not be revealed, but it shall certainly be indicated that this research is conducted with the request or support of a pharmaceutical company.

Reporting format

4.35 EFPIA have provided a 'Model of a Standardised Template' – the suggested reporting format for disclosure data. EFPIA country associations may provide their own template based upon the EFPIA one.

Information to be disclosed

4.36 The following types of data MUST be recorded for a full calendar year on the appropriate template and disclosed:

- For each individual HCP that gives consent for their personal data to be used in this way:
  - Full name and address of principal practice;
  - Fee for service and consultancy – Market Research incentive;
  - Market Research–related expenses.
- Where only aggregate data can be given (where consent has not been given for personal data to be used in this way):
  - Aggregate amount attributable to transfers of value to recipients i.e. the incentives and expenses (separate totals) for Market Research;
  - Number of recipients in the aggregate disclosure;
  - % of recipients included in the aggregate disclosure as a proportion of the total number of recipients disclosed (individual and aggregate).

Country of disclosure

4.37 Disclosures MUST comply with the national (EFPIA member) code of the country where the HCP receiving payment has their principal practice. The address of the HCP's principal practice should be used as the reference when determining in which country the data should be disclosed.

Public disclosure

4.38 EFPIA have advised that public disclosure can be via either:

- The relevant Member Company's website or
- A central platform provided by a government, regulatory or professional body or an EFPIA member/country association.

Individual country/member associations decide upon the route.

Disclosed data will be publicly accessible in the country where the HCP has their practice.

Reporting responsibility

4.39 Pharmaceutical companies MUST complete and post the disclosure data on their company website or forward it to a central platform – as required in their country.

Reporting timetable

4.40 Disclosures MUST be made in the first six months after the end of the calendar year in which the Market Research payment was made.

Consent and record keeping required

4.41 HCPs whose identity will be known to the commissioning pharmaceutical company MUST be advised that disclosure will take place and asked for their consent to pass on their personal data and payment information for this purpose. This must take place as soon as practical, generally at recruitment.

As with any request for consent for the use of personal data, the following must be made clear:

- The purpose for which the individual's personal data will be used – why it is requested;
- The consequences of giving (how their personal data will be used) or not giving consent;
- Market Research subjects' agreement or refusal must be recorded.

4.42 When securing consent to transfer personal data to the pharmaceutical company for disclosure the GDPR requires that the recipient company is identified. As disclosure reporting is a separate processing operation (to the Market Research), consent for this may be secured at the end of the interview.

4.43 Market Research agencies MUST keep records of the required disclosure information to pass to the pharmaceutical company.

4.44 Pharmaceutical companies MUST keep records of the required disclosure information, collate it, then complete and upload the appropriate data collection template.

4.45 Pharmaceutical companies may need to review their disclosure policy and procedures for Market Research payments with their legal and/or compliance departments.

4.45.1 **In Denmark** legislation stipulates that any non–double–blinded (i.e. the identity of the commissioning client company in not known to the HCP Market Research subject and the identity of the HCP is not known to the commissioning client company) and the contact between a HCP and a pharmaceutical company or manufacturer of medical devices must be declared to the Danish Health authorities as consultancy. The registration of contact must be made by both the HCPs and the end–client (Pharmaceutical Company or Medical Device Manufacturer).

4.45.2 **In France** two different legislations regulate disclosure

- **Loi Bertrand**[19] – is applicable to all companies operating on the French market, regardless of whether the company is based in France or working from outside France. The law covers fieldwork commissioned to take place with healthcare professionals in France irrespective of where the individual, team or company that is paying for, designed or is undertaking the work is based. In essence, it is necessary to disclose: any contract or agreement with a recipient – this includes contracts of any nature, in particular R&D contracts (clinical trials, observational studies…), as well as other consultancy agreements (speaker, proctoring, advisory boards…), and this also includes the so–called "hospitality conventions" (invitations to individuals HCPs at scientific or medical events for which covered companies pay the related costs, such as registration fees, travel costs, meals and accommodation expenses) – except agreements entered into in the context of commercial relationships; any benefit in cash or in kind granted to a covered recipient beyond 10 Euros.
- Loi Anti Cadeaux/Loi DMOS (Diverses Mesures d'Ordre Social) requires that the relevant national association/board e.g. the CNOM (physicians) or the CNOI (nurses) etc., is informed of agreements between companies/agencies and healthcare professionals including market research studies, one month before they begin.

Further information upon Loi Bertrand and Loi Anti–Cadeaux may be found within the Country News, France section of EphMRA's website.

4.45.3 **In the USA** generally speaking the federal Sunshine Act does not include mandatory disclosure of survey incentives made by pharmaceutical companies or their agents to doctors. While survey payments were included in initial versions of the law and have been the subject of ongoing debate in Congress, the law generally excludes thank you payments for taking part in surveys provided the company sponsoring the research is unaware of the Market Research subjects' identity. However, some state laws are different. Insights and Intellus have advised that to their knowledge the Sunshine Act does not require agencies to identify to client companies the names of healthcare professionals who report adverse events. For further information see: https://www.insightsassociation.org/article/final–physician–payments–sunshine–act–rules–released

For further details upon US state Sunshine laws see:

http://www.policymed.com/2014/04/physician–payments–sunshine–act–review–of–individual–state–reporting–requirements.html

Re–contacting Market Research subjects

4.46 Under GDPR, you can only re–contact Market Research subjects if they have a lawful basis e.g. consent for this. So, if you think you might wish to contact a Market Research subject again (even if only for simple clarification), you MUST obtain their consent before the end of the interview. When children are researched consent for re–contact should be sought from the responsible adult and the child separately.

4.47 You don't need to obtain their consent before re–contacting them for Market Research quality control purposes or data validation, these would be very likely to be in the data's controller's legitimate interests, but this must be subject to assessment.

19 Law No 2011–2012 on the Strengthening of Health Protection for Medicinal and Health Products (loi relative au renforcement de la sécurité sanitaire du medicament et des produits de santé

4.48 Market Research subjects agreeing to re–contact MUST be fully informed of the purpose of re–contact and who will make it. Re–contact questions should reflect the possible reasons for the re–contact, such as for a second stage of the study, to ask a question missed or further explore a particular issue. The question "May we contact you for future research?" is not sufficient to allow re–contact, this type of standard question is really panel building question as it asks about any other projects occurring at an unspecified future time.

4.48.1 **In Germany**, if personal data is stored for re–contact for which informed consent has been given, the personal data MUST be stored separately from any additional data about the individuals. The merging of data for the specific selection of Market Research subjects is done by means of a code number.

4.48.2 **In Australia** researchers may use identifiable research information to make further contact with participants for a research purpose provided that: a) If re–contact of an individual who initially declined to participate is involved, the Researcher and the client have genuine research concerns that warrant such recontact; and b) If re–contact of an individual who has participated in a project is involved: ie. the individual was informed of this likelihood at the time the information was collected, except where the Researcher and the client have reasonable grounds to decide that there are genuine research concerns that justify not so notifying; or ii. any individual who, at the time of collection, indicated a wish not to be re–contacted for research purposes is excluded unless the Researcher and the client have reasonable grounds to decide that there are genuine research concerns that warrant the individual's inclusion.

Incentives

4.49 An 'incentive' is any benefit given to a Market Research subject to encourage participation in a Market Research study and should be:

- Dependent only on the completion of a questionnaire/interview and not on any additional conditions in the case of one–off surveys;
- Kept to a minimum;
- Appropriate to the time involved;
- No more than the fair market value for that individual's professional consultancy or advice;
- Appropriate to the Market Research subject type;
- Appropriate to the task(s);
- For patients/members of the public it is a token of appreciation – not a fee for time;
- Handled only by the agency however if the Market Research is conducted by a company's in–house researchers, Market Research subjects' personal data MUST NOT be accessible to company personnel outside the research team.

Market Research subjects must be clearly informed:

- Who will administer the incentive;
- What the incentive will be;
- When the participant will receive the incentive;
- If any conditions are attached e.g. completion of specific tasks or quality control checks.

4.50 Panel members should be made aware of the approximate level of commitment and/or length of time required before the incentive will be paid.

Country Exceptions

Please refer to Incentives Overview Country Differences and Summaries by Market

Published in 2019 and available at www.ephmra.org

Incentives that are Not Allowed

4.51 Incentives are not allowed in the following situations:

- That could influence opinion or behaviour e.g. to encourage use of a drug; excessive payments that could be seen as an attempt to buy good opinion or reward use;
- That require the Market Research subject to spend money;
- That are made up of the sponsoring client's goods, services or vouchers for these;
- As a covert means (alongside supposed Market Research questions) to collect personal data.

Free Prize Draws

4.52 With regard to free prize draws, i.e. a draw where prizes are allocated by chance, with no payment to enter, Market Research subjects MUST NOT be required to do anything (other than participate in the Market Research) to be eligible for entry to a free prize draw. 'Free' includes any method of communication (post, telephone or other) at a standard rate.

National laws governing free prize draws vary widely in Europe, so care must be taken to ensure the prize draw is carried out in compliance with local law, including registering the draw with the relevant authority and arranging for the draw to be administered by public notary or other official as required by local law.

4.52.1 **In the UK** MRS Regulations for Administering Incentives and Free Prize Draws July 2015[20] provide further details of the rules.

4.52.2 **In Mexico**, the Secretary of Governance is responsible for authorising prize draws. There are specific requirements including registration for prize draws open to the public. Legal counsel should be obtained in order to determine if a prize draw or raffle within a specific survey population should be considered a public or private / closed event.

4.52.3 **In the USA** 'Rules Governing Sweepstakes' are provided by Insight Association and available to members on the website www.insightassociation.org . It specifically states that "this is an evolving body of law" and that "it is not possible to construct a set of rules and practices that we can guarantee will comply with every applicable law. Anyone running sweepstakes, especially online, should have their counsel carefully monitor state and federal legislation and court decisions in this area."

Confidentiality of Recipients' Incentive Data

4.53 The personal data of Market Research subjects eligible for incentives are confidential, so cannot be passed to clients without a lawful basis such as consent, this consent MUST NOT be linked to receipt of an incentive.

Storing Incentive Details

4.53.1 **In Germany** and in Italy tax laws make it necessary to store the private address data of Market Research subjects receiving incentives for the length of time required by tax law. In Germany in this case, the address data must be kept for the period required by tax law in a form that shows the date of participation, but does not allow merging with the data collected.

4.53.2 The same is true **in Poland** for incentives above a specific level.

4.53.3 **In the Netherlands** tax laws make it necessary to store the confirmation of receipt of incentives, for the length of time required by law. Personal data MUST be stored in a way that ensures the date of the interview is identifiable but prevents personal data being linked to response data.

20 https://www.mrs.org.uk/pdf/Regulations%20for%20Incentives%20and%20Prize%20Draws%20July%202 015.pdf

5. DURING FIELDWORK

Information to be Communicated at the Start of Fieldwork

5.1 Before fieldwork starts all of the information detailed in section 4.20 MUST be communicated to Market Research subjects.

5.2 EphMRA does not recommend the use of sales representatives as Market Research interviewers.

Instrument and Stimulus Design and Use

Questionnaire and Question Design

5.3 Researchers should take reasonable steps to ensure that:

- Questions are fit for purpose and clients have been advised accordingly;
- Questionnaire design and content are appropriate for the audience being researched;
- Market Research subjects are able to answer the questions in a way that reflects the view they want to express, including don't know/prefer not to say where appropriate;
- Market Research subjects are not led towards a particular answer;
- Answers are capable of being interpreted in an unambiguous way;
- Personal data collected is relevant and not excessive[21].

5.4 Market Research materials should not:

- Raise unfounded hopes for a treatment;
- Mislead Market Research subjects with regard to the performance of a product;
- Encourage members of the public to ask a healthcare professional for a particular product or healthcare professionals to use or recommend a particular product – disguised promotion is prohibited.

Sensitive Topics

5.5 When a topic is considered sensitive, Market Research subjects MUST be told explicitly the subject and content of the discussion. Sensitive topics include those that are judged to be sensitive to most people or a specific group of people because of the nature of the subject or those that may be sensitive to a particular individual, because of that individual's past history.

5.6 When sensitive topics are to be discussed, the Market Research subject MUST be made fully aware of:

- The topic for discussion prior to the interview;
- The fact that they need not answer all of the questions posed;
- Their right to withdraw at any point in the recruitment or interview process.

5.7 In cases where the subject under discussion is gender specific or of a sensitive or potentially embarrassing nature, Market Research subjects should be interviewed by interviewers of the same sex or given the choice to be so.

5.8 If collecting information on sex, gender or age may prove sensitive, the following guidance may be helpful, the UK MRS's:

- Guidance Note on Collecting Data on Sex and Gender, January 2016[22]
- Guidance Note on Researching Age Bands for Over 65s, July 2016[23]

Stimulus Material

5.9 Stimulus material includes any material shown during the course of fieldwork e.g. product profiles, branding concepts, devices, packaging materials.

21 https://www.mrs.org.uk/pdf/2014–09–01%20Questionnaire%20Design%20Guidelines.pdf

22 http://www.mrs.org.uk/pdf/Guidance%20on%20Collecting%20Data%20on%20Sex%20and%20Gender.pdf

23 https://www.mrs.org.uk/pdf/MRS%20Best%20Practice%20Guide%20Age%20bands%20for%20researc hing%20over%2065s.pdf

5.10 Stimulus material should be fit for purpose. Pharmaceutical industry codes of practice generally require that information claims and comparisons be accurate, balanced, fair, objective, and unambiguous, be an up–to–date evaluation of all the evidence and they should not mislead either directly or by implication, by distortion, exaggeration or undue emphasis – the same is expected of stimulus material.

5.11 Within any Market Research care should be taken to ensure that Market Research subjects understand when they are providing feedback on draft materials, hypothetical scenarios, assumptions, a product in development or as yet unlicensed.

5.11.1 **In the Netherlands** MOA affiliated researchers MUST NOT use stimulus with healthcare professionals that includes brand names or indications for unlicensed products. The use of samples of prescription only medicines is also prohibited in Market Research.

5.11.2 **In the UK** MR testing of promotional messages or materials (e.g. to assess reaction to them before or after launch) is allowable – there are no laws or industry regulations (healthcare or MR) that prohibit it. However, it is essential that the reasons for their use are clearly and directly linked to bona fide MR objectives and the work is carried out in compliance with the BHBIA's Guidelines. It would also be necessary to make sure respondents understand the nature of the MR and are advised in advance that they will be asked about their reactions to promotional materials/messages and are protected from disguised promotion

5.12 Where required (country requirement or company policy) stimulus materials to be used within Market Research should be approved by the client company's medical department prior to use (irrespective of format or finish).

5.13 Companies may want to consider the need for Market Research subjects to sign some form of confidentiality or non–disclosure agreement if commercially sensitive information is shared with them and the Market Research subject is made aware of the identity of the end client company.

5.14 All stimulus materials should be collected at the end of the interview.

Use of Products Names

5.15 The unnecessary or repeated use of brand names should be avoided unless assessing reaction to the name, or use of the product by name is an essential research objective, particular care should be taken if the names of unlicensed products are to be used

5.15.1 **In Italy** the use of brand names when researching hospital 'H' drugs with patients although not explicitly forbidden would be considered unethical.

5.15.2 **In Spain** the Spanish Code of Good Practices for the Promotion of Medicines and Interaction with Healthcare Professionals requires that there is no link between the product tested and a company, so product testing should be blinded.

Testing Products

5.16 Companies should generally refer to their medical and regulatory departments for guidance on Market Research surveys that involve testing products.

5.17 It is strongly recommended that placebos are used during Market Research surveys whenever practical.

5.18 Guidance for testing products via Market Research varies depending on the category a medication falls into:

- Licensed prescription–only medicines taken in line with the license can only be taken by a Market Research subject who is an existing user of the product and if a registered medical practitioner is present;
- If a medicinal product is licensed but the Market Research subject is asked to use the product outside of its approved indication(s)/dosing/formulation i.e. as an 'investigational product' during a Market Research survey, it is recommended that the research is carried out according to Good Clinical Practice (GCP) guidelines;
- If the medicinal product is unlicensed, Good Clinical Practice (GCP) guidelines MUST be followed when undertaking a Market Research survey.

5.19 If subjects are taking non–prescription drugs (i.e. over the counter – OTC) during Market Research surveys, it is recommended that an appropriate healthcare professional is present.

5.20 For Market Research involving medical devices or diagnostics only (i.e. there is no active ingredient involved), if the device is not CE marked, is an implantable device, is to be used outside the approved license or could potentially cause a patient harm (e.g. use of a needle is involved), the commissioning client company's medical department MUST approve the Market Research approach, confirm whether the Guidelines on Medical Devices (MEDDEV 2.7/4) need to be followed and whether an appropriate healthcare practitioner should be present.

5.21 When the client entrusts products to an agency researcher's care, the client commits them self to providing products compliant with laws in force and to give all the necessary information on these products, providing in particular correct information on the directions for use, the ingredients list and the transport and storage conditions. Moreover, the client MUST take the necessary measures to provide the researcher with any constraints relating to the security of the products.

5.22 Clients are fully responsible for all damage or injury to researchers or respondents caused by materials or products they have provided to researchers for research purposes unless the researcher or respondent failed to follow the care instructions provided by the client when the materials were in the agency's possession (or the agency breached any other legal obligations as with stimulus material, all products should be collected at the end of the interview.

5.23 Adverse Event reporting requirements associated with medical devices should be agreed with the Marketing Authorisation Holder before commencing any Market Research survey.

Recording and observation of Fieldwork

Definition of personal data

5.24 Personal data includes sound and image data e.g. non–anonymised audio recordings and video footage of an individual from which it could be possible to identify the individual.

Image data will always be personal data, a voice alone, may or may not be. If an individual belongs to small universe e.g. they are a KOL and have a distinctive accent, then voice alone is likely to be an identifier; however a GP's voice with a non–descript accent listened to out of area is not likely to be identifiable data in isolation.

Consent Required

5.25 Market Research subjects MUST be made aware at the time of recruitment if their input is to be recorded or observed (even if it only for analysis purposes by the agency) and why it is proposed. Market Research subjects MUST always give their consent for this and consent must be recorded.

5.26 At the start of fieldwork Market Research subjects MUST be informed if their personal data is to be passed on to the commissioning client company.

5.27 Market Research subjects' documented consent for audio or video recording should be obtained at the beginning of the interview before recording commences. Where multiple purposes exist or are possible, separate consent for each purpose should be obtained. Combining non–research purposes with Market Research is prohibited by Market Research industry guidelines in Germany, adverse event reporting within the context of a Market Research project is considered a Market Research activity.

Information to be Communicated to Market Research Subjects when Observed by Client

5.28 When the end commissioning client is viewing non–anonymised fieldwork live or at a later date via streaming or video–relay this is a transfer of personal data, consequently in order to meet the requirements of informed consent, Market Research subjects MUST be told:

- The name of the recipient company;
- If naming the recipient company is likely to impact on the integrity of the Market Research the company name can be withheld until the end of the interview if Market Research subjects agree. However, if Market Research subjects do not want their non–anonymised input to be viewed this MUST be respected;
- Why they are viewing – different purposes require separate consents;

- Who (in terms of role/position not names) will see/listen to it;
- Of the countries outside their own to which non–anonymised information will be transferred or viewed e.g. inform Market Research subjects filmed in France that the film will be viewed in the USA;
- Of their right to withdraw consent;
- How and who to contact within the Market Research agency with any questions or concerns.

In most countries the data protection/privacy regulator will require the name of the company receiving personal data to be revealed to the Market Research subject. This is a GDPR requirement.

When live observation takes place via a one–way mirror or sitting in there is no transfer of personal data to the commissioning client company so the client's identity does not need to be revealed and should not be revealed without the company's permission. **In Germany** Market Research guidelines require that the client's identity must be revealed if requested.

When live viewing takes place via video relay/streaming (with and without archiving), data protection requirements mean you must name the organisation(s) viewing before transfer of the personal data takes place. So if for example, the end client is viewing fieldwork live via a video–stream the client's identity must be revealed before fieldwork as part of the information communicated to secure Market Research subjects' informed consent.

When delayed viewing takes place via video relay/streaming (with and without archiving), if the end client wants to view or listen in to fieldwork after it has taken place, consent for this must be secured before the interview. However, the client's identity may be disclosed at the end of the interview (before any personal data is shared with the client) if naming the end client beforehand would undermine the integrity of the Market Research but:

- Market Research subjects must be made aware at recruitment that:
  - the client will be named at the end of the interview;
  - they can withdraw their consent at any point.
- The justification for this should be documented.

5.28.1 **In Australia** participants must be informed before observation techniques or recording equipment are used for a project, except where these are openly used in a public place and no identifiable research information is collected. Comment: Rule 11 states that Researchers must obtain consent from participants to disclose their identifiable research information. This includes disclosure to observers of an interview or group discussion, as people's faces and voices are defined as identifiable research information. This applies to all observation techniques and recordings, whatever the medium: including, but not limited to, face to face, audio or internet based. If a Researcher has agreed with the client that observers are to be present, the Researcher must inform all observers about their legal and ethical responsibilities. Researchers must make clear to participants the capacity in which observers are present; any clients must be presented as such, even if they are also professional researchers and/or Members of The Research Society.

5.28.2 **In Canada** the purpose of a market research program and, if applicable, the use of recording devices and presence of research "Viewers" must be made clear to participant(s) at the start of the interview. The research Viewer(s)'s identity must remain anonymous to participants to preserve respondent objectivity. Due to confidentiality of respondents, Viewers may not include Researcher sales representatives or any other field–based personnel who have contact with and the ability to influence respondents/participants.

Even when a consent form is signed, the confidentiality and anonymity of participant(s) and their individual responses must be preserved to the fullest extent possible. The identity of the participant(s) must not be revealed for purposes of promoting Prescription Medicines to them in the future. The purpose of the market research as well as the way the responses (individually or aggregated) will be transmitted to the Researcher should be transparently stated in the consent form.

Direct contact with the participant(s) in the market research project, in which the identity of the sponsoring company is intentionally masked, should be limited to marketing research personnel only with no Researcher sales representatives' influence or involvement. There should be no follow–up by sales representatives or staff derived specifically from these market research projects.

5.28.3 **In Japan**[24] Considerations when Observing (Qual. Research). Receive a signed consent agreement from the research participant (pharmaceutical company) prior to conducting the research. Be very careful as to not let the observer (pharmaceutical company) and MR subject come into contact.

- Please make sure that the pharmaceutical company also has a thorough understanding of observer–related issues.
  - Please make it a practice to receive a signed consent form for participation via Focus Vision.
- If a respondent (e.g. physician) and a participant (observer) accidentally see each other at the interview facility, the participant is to be excluded from observing the interview.
- Participants are forbidden from using media (e.g. internet) to look up physicians or facilities during the interview.
  - If the participant discloses the search results to another participant, please immediately have that participant removed from the venue.
- A participant who knows of the respondent can still participate provided they do not disclose that information.
- Hard copies, notices, and other documents containing the name of the research agency, are to be examined. Pharmaceutical companies are also advised to raise awareness of this internally. (especially to non–research depts.)

Passing on Recordings without Consent

5.29 Recorded data (audio or video that could identify individual Market Research subjects) given to clients without Market Research subject consent MUST be anonymised.

5.29.1 **In Japan** considerations of Recorded Media Deliverables: Visual/audio recordings should generally not be delivered. If delivering: 1) both must be altered and edited; 2) a consent form specifying the terms of use must be made.

- Visual/audio recordings should generally not be delivered. If they need to be delivered, they must be blurred and/or edited.
- Visual/audio materials may be viewed at a facility specified by the research agency. However, these materials may not be "lent out" to be returned later.
- Please limit the internal viewing and sharing of delivered DVDs/recordings (only in a closed environment).
- External use of recorded media requires the consent of the MR subject, so please receive confirmation from the research agency. The research agency may require confirmation as to who will hear/see the deliverables in advance.
- If pictures are to be delivered (e.g. office visits or photo researches), anything in the background that legibly shows the hospital or physician's name must be edited out.
- When conducting research from overseas (global pharmaceutical/medical device /agencies), there must be a guarantee that the recorded media will not be delivered or provided to a Japanese subsidiary. Confirm whether there is a possibility that information on the physician (regardless of format) could be provided to the MRs of the Japanese subsidiary. Additional practical information is available here: Handling Personal Information & Observing/ Distributing Recorded Video.

When a Market Research Subject Withdraws

5.30 If a Market Research subject withdraws from the research at any stage e.g. during a group discussion, their personal data MUST not be processed anymore and their anonymised input should be withdrawn from the final analysis and reporting, if they request this.

24 https://www.medi–ken.org/pdf/mediken_202002_e01.pdf Handling Personal Information When Conducting Market Research May 2019

Delayed Viewing of Fieldwork e.g. by video streaming

5.31 To ensure that unauthorised viewers cannot access recorded material EphMRA recommends that the commissioning agency/client ensures that:

- Comprehensive security measures are in place;
- Access is password protected and restricted to authorised users (identified through a unique login id) and that login ids/passwords are distributed only by the project leader;
- Authorised users agree in writing not to allow access to unauthorised personnel *(see pro forma 4 – Client Agreement to Safeguard Confidentiality of Recordings)*.

Recordings should not be archived for no longer than is required to fulfil the purposes of the study. **In Germany**, Market Research industry guidelines state that end clients must destroy copies of non–anonymised recordings after 3 months.

5.31.1 **In Germany**[25] the observation of a group discussion by means of a one–way–mirror is a procedure which is to be treated as equivalent to observing the discussion at the same time via a monitor. It is therefore acceptable subject to the same requirements as those for a monitor – see 5.33.1. Observations of the behaviour of single individuals carried out in the (own or rented) premises of the research agency about which the persons in question cannot be told in advance for methodological reasons (e.g. studying the reading behaviour while leafing through a magazine) must not take place in a situation where the observed person is completely alone in a room and may thus assume himself/herself to be unobserved. Instead of informing the person beforehand he/she shall be informed afterwards and asked to allow the recording, or the observation result obtained in another way to be used for the purpose of the study. General information given before the observation was made (e.g. asking the individual to come into a studio and take part in a test there) does not replace the subsequent consent to using the observation.

Listening In or Audio–only recordings

5.32 If it is possible that the Market Research subject could be identified by the audio–recording alone they should not be passed to client companies unless there is a lawful basis in place e.g. the Market Research subject has given their informed consent.

5.32.1 **In Germany** if the client commissioning a group discussion wishes to get an idea of the course of such a discussion on his own – beyond the report submitted by the agency conducting the research – this request may be granted subject to the following conditions:

- A client representative observes the course of the group discussion or a single interview via a video recording in the premises of the research agency either at the same time (via a monitor in a neighbouring room) or by watching the video at a later time. This procedure is acceptable if the participants have been informed previously and have expressed their consent.
- A client representative takes part in the group discussion after having been introduced to all participants in his capacity as a client. There are no legal reasons against this procedure, however – depending on the topic – methodological ones may exist.
- A client representative takes part in the group discussion but does not make himself known as such. This procedure requires that his participation is necessary for achieving the research goal and that compelling methodological reasons exist that prevent his capacity as a client from being made known.
- The client receives the video tape(s) for research purposes. In this case it is necessary that:
  - The client signs the undertaking available here https://www.adm–ev.de/wp–content/uploads/2018/11/RL01_E_Group–Discussions_2006_%C3%9CBERGANG.pdf and hands it over to the research agency before receiving the recording and
  - All participants have been informed drawing their attention to the undertaking and have expressed their consent.
  - The client's participation in the group discussion in form of a video link–up at the same time is equivalent to handing over the video tapes subsequently. It is therefore subject to the same restrictions.

25 https://www.adm–ev.de/wp–content/uploads/2018/11/RL01_E_Group–Discussions_2006_%C3%9C BERGANG.pdf

- Condition for all listed versions is that one can reasonably assume that the participant(s) is/are not known to the client (including the client's staff and external consultants) because of the selection criteria.

Client Awareness of Restrictions on use of Recorded Data

5.33 Clients should be made aware of the restrictions on the use of recorded data at the start of a project if they might want to watch, listen to or view copies of recordings during or after the project.

Protecting Data When it is Transferred

5.34 In transferring personal data agencies must comply with chapter 2.

Observers' Guidelines

5.35 When client observers are introduced, they do not need to be introduced by name. It is sufficient to tell Market Research subjects the nature of their roles within their company and in general terms their reasons for observing. Clients or their sub–contractors MUST NOT be passed off as members of the Market Research agency.

5.36 Observers should be informed of their responsibilities towards Market Research subjects and agree to:

- Withdraw from observing if a Market Research subject is known to them/recognised to protect the Market Research subject's anonymity. If an observer knows that they will subsequently have to deal with a Market Research subject, the attendee MUST also withdraw. However, if Market Research subjects are made fully aware of the presence of an observer known to them and give explicit consent for that individual to observe then that person may remain at the session, however care should be taken to ensure that Market Research subjects are completely comfortable with this.

5.36.1 **In Canada**, observers should be told that if they find they know any of the participants, they must stop observing and notify the researcher.

5.36.2 **In Japan**, if a (HCP) Market Research subject is known to an observer, the observer MUST sign an agreement that they will never disclose information gained while observing, never make any notes, and never use directly or indirectly the information for sales/promotion activities.

5.36.3 **In Canada**, MRIA members must make sure that any observer of fieldwork or recipient of a fieldwork recording is aware of the requirements of the MRIA Code and the need to abide by these.

6. AFTER FIELDWORK

Analysis and quality control

6. Researchers and agencies should anonymise or pseudonymise personal data as soon as possible during the Market Research process.

6.1 Researchers must when requested by clients allow independent checks on the quality of data collection.

Storage and Security

Consent for Storage of Personal Data for Future Use

6.2 Personal data e.g. contact details should only be stored for future use if consent has been given.

Storage Duration

6.3 Personal data MUST be destroyed as soon as the purpose for which it was processed is redundant.

6.3.1 **In Russia**, personal data should not be stored for longer than it is needed for processing unless the personal data retention period is established by a federal law or a contract.

6.4 The researcher/agency should store research records for an appropriate length of time – there are no absolute guidelines on how long this should be. This period will vary according to the nature of the data, the type of project and the need for future research or follow up analysis. Personal data (such as recruitment questionnaires) can be destroyed before non–personal data (such as tabulations).

Security

6.5 All those processing personal data should have a data breach notification policy in place.

For more information on data breaches please see the EphMRA guide 'GDPR Data Security' available to members on the EphMRA website.

6.6 The data disposal method should be appropriate to the sensitivity and confidentiality of the data.

6.7 If video streaming has been used to allow remote viewing of fieldwork it is possible that the video transmission system used delivered a copy of the recording to the receiving computer. If this was the case the researcher MUST take steps to ensure that any copy of the video stream saved on the observer's computer is deleted.

Reporting Market Research

6.8 Researchers should take reasonable steps to ensure that:

- Interpretation and conclusions are adequately supported by the research findings, with explanation as to which data support the interpretation;
- The detail necessary to assess the validity of findings is available (including sample size, question source, statistical tests used) and that data tables include sufficient information to enable reasonable assessment of the validity of the results;
- Reports and presentations accurately:
  - Reflect the findings of the research.
  - Reflect the researcher's interpretations and conclusions.
  - Distinguish between factual reporting of data and a researcher's interpretation. And that the content does not breach any copyrights.

6.9 Combining data is permissible as long as personal data is not released to the client company when data is combined and combining the data does not enable the client to identify the Market Research subject.

6.10 Personal data MUST not be included in reports unless there is a lawful basis for this e.g. consent has been given. If personal data is included in the report the client as the recipient of personal data will need to be identified to the data subjects whose personal data is used.

6.10.1 **In Japan** qualitative/quantitative research results that could lead to the identification of individuals will not be provided in the deliverable data (will not be delivered).

- Data that could lead to the identification of individuals such as names, facility names, and DCF codes, will not be included in the deliverable data (it is allowed within the research, but the data will not be delivered);
- Answers from university hospital/advanced treatment hospital physicians that include data on their location, job title, or age, will not be included in the deliverable data (it is allowed within the research, but the data will not be delivered);
- If combining multiple flags could lead to personal identification, those flags will not be included in the deliverable data (it is allowed within the research, but the data will not be delivered);
- The deliverables will be tabulated data;
- In principle, KOL surveys should not be conducted within quantitative research. Please conduct questions about KOLs after consulting the research agency. e.g. Even if they are a doctor, it is unlawful in most cases to publicly release their name without consent, unless they are a public figure. Note: Executive positions (e.g. president, hospital director) are public figures; medical department heads are private figures.

Publishing Market Research

6.11 The client should not publish any of the results of the survey without the approval of the agency unless otherwise agreed in advance.

6.11.1 **In Spain**, Market Research studies not published in renowned scientific/medical publications (i.e. NEJM, Lancet, etc.), cannot be used as references for prescription medicines promotional materials

6.11.2 **In Turkey**, the AIFD Code of Good Promotional Practice and Good Communication 2015 5.2, states that the use of IMS grid sales data in promotion does not conform to the Code.

6.12 Researchers should check any client–prepared materials prior to publication to ensure that the research results are not misleading.

6.13 Full details of the source should be referenced and must include detail that will allow the audience to assess the quality of the data and the validity of the conclusions. The material included must not breach copyright.

6.13.1 **In the USA**, Insight Association members are obliged to disclose the:

- Sponsor of the study;
- Description of the study's purpose;
- Name of the research organisation conducting the study;
- Method of data collection;
- Date(s) of data collection;
- Sampling frame, method and size;
- Exact wording of the questions;
- Calculated margin of error for quantitative studies.

IA Code of Standards and Ethics for Marketing Research and Data Analytics

https://www.insightsassociation.org/issues–policies/insights–association–code–standards–and–ethics–market–research–and–data–analytics–0

6.13.2 **In the Netherlands**, MOA affiliated researchers commit themselves to sending out a research framework, when sending out press releases intended to publish research findings. The request is made to both the external media, and to the internal press services, to add the framework at the bottom of the article.

6.14 If research is misreported by a client, the researcher should as soon as possible:

- Refuse consent for their name to be used in connection with the misreported findings;
- Publish a statement that the results have been misreported and correct the misreporting;

7. RESEARCHERS' RESPONSIBILITIES BY RESEARCH APPROACH

Face to Face Methodology

7.1 It is good practice for the interviewer to provide an identity card to the MARKET RESEARCH subject.

Telephone Methodology

Unless otherwise stated the guidelines below apply to both telephone research using mobile phones and fixed–line calls.

Naming the Agency/Researcher

7.2 The interviewer MUST give the name of the agency that they represent and MUST give their own or an agreed contact name.

Do not call lists

7.3 Do not call lists specific to Market Research must be respected.

Special Precautions When Contacting Mobile Phones

7.4 Researchers should take special care when contacting Market Research subjects via mobile phones (whether by voice, text or email), with regard to Market Research subject safety and privacy:

- It is recommended that interviews by mobile/WAP phone are preceded with a question such as "is it convenient to proceed with this interview now?"
- The Market Research subject should be told the likely length of the interview;
- It may be more convenient to arrange an appointment to call back at a different time or via a land line;
- Researchers should try to establish as early as possible if the number to be contacted / contacted is that of a mobile or a fixed–line telephone.

When calling mobile phones researchers should recognise that even where legislation restricts unsolicited calls for commercial purposes but not Market Research, it is important to consult and apply any existing research–specific do–not–contact lists for mobile and fixed line phones.

Use of Unsolicited Texts for Recruitment

7.5 ESOMAR advises against the use of unsolicited text messages to recruit Market Research study Market Research subjects and provides a 'Summary of regulations covering unsolicited contacts (business to consumer)' May 2013, this is available on the ESOMAR website[26].

Use of Apps

7.6 You must have a lawful basis e.g. Market Research subject consent for the use of an app and Market Research subjects MUST be made aware of its purpose, the type of data it collects and its impact on functioning or performance such as degradation of battery life. For further details see ESOMAR's Guideline for Conducting Mobile Market Research.

It is suggested that legal advice is sought if an app uses a location device or tracks activities without user engagement (e.g. passive listening) to ensure that data protection and privacy rights are not contravened.

Country Specific Guidance

7.6.1 Regulations in force **in Canada** could potentially establish legal liability for researchers contacting potential Market Research subjects via a mobile device. In general, researchers must not make unsolicited email approaches to potential participants unless individuals have a reasonable expectation that they may be contacted for Market Research due to a pre–existing relationship with an organisation.

7.6.2 **In Germany** and **in the UK**[27] the use of predictive/auto–diallers is restricted.

7.6.3 **In the USA** they are permitted only if the Market Research subject has given prior explicit consent. When they are used, "abandoned or silent calls", (i.e. there is no live interviewer) immediately available, are not allowed.

7.6.4 **In Germany** telephone interviews that are in any way directly linked with telephone marketing are prohibited. For further details upon telephone interviewing in Germany see Guidelines on Telephone Surveys published by the German Market Research organisations

7.6.5 **In the Netherlands** the 'Onderzoekfilter' is set up specifically for registering 'do–not–call' requests regarding Market Research. Research agencies affiliated to the MOA, the FEB and the VSO, the associations of the market and policy research, MUST check the available phone numbers at the 'Onderzoekfilter' before starting any unannounced telephone surveys.

26 https://www.esomar.org/uploads/professional_standards/guidelines/ESOMAR–Codes&Guidelines–Legi slative–issues–unsolicited–contacts.pdf

27 https://www.mrs.org.uk/pdf/2012–02–23%20Regulations%20for%20Predictive%20Diallers.pdf

7.6.6 **In the USA** the Insight Association Code of Standards and Ethics requires research organisations to verify that individuals contacted for research by email or text message have a reasonable expectation that they will receive email or text message contact for research (and provide further detail upon what constitutes 'reasonable expectation').

7.6.7 **In the USA** the Federal Government has recognised the distinct separation between survey research and telemarketing. The restrictions included in the 1995 Telemarketing and Consumer Fraud and Abuse Prevention Act, the 1991 Telephone Consumer Protection Act, and the 2003 National Do Not Call Registry apply to telemarketing and NOT to Market Research calls. Under the laws, calls made for sales–related purposes MUST comply with the 'do–not–call' request of the person called. Telephone calls for survey research purposes are not bound by these provisions, although companies should be careful in drawing this line and should be aware of ongoing debate and concern about survey activities by some regulators and legislators. However, Insight Association members maintain internal do–not–call lists of those individuals who have specifically requested not to be contacted by that company for participation in survey research. FCC Regulations (October 2013), permit Market Research calls made to mobile phones using an auto–dialer only with the "prior express consent" of the intended recipient to receive such calls.

7.6.8 **In the USA** there is a federal prohibition on calling:

- A doctor's office or a healthcare facility where the called party is charged for the call or in such a way that 2 or more telephone lines of a multi–line business are engaged simultaneously;
- Cell/mobile phones with an auto–dialler (any equipment capable of dialling a telephone number prior to a live operator being available to exclusively handle the call). In addition, operators of automated dialling equipment need to remove any number classified as a public safety answering point (PSAP), in line with the Telephone Consumer Protection Act (TCPA).

Ethnographic/Observational Approaches

Definitions

7.7 Observational or ethnographic research are defined as any research form which relies significantly upon the observation of human behaviour as one of its data sources, whether Market Research subjects are openly observed (participant observation) or covertly or indirectly observed (non–participant).

7.8 Images of people on film and audio recordings of them would be considered as personal data under Data Protection legislation Guidelines

7.9 When conducting ethnographic Market Research researchers are advised to:

- Inform Market Research subjects of the overall reasons for the observation of their behaviour;
- Clarify in writing and gain documented agreement as to the precise nature of the research and the responsibilities of each party;
- Inform Market Research subjects of the extended nature of ethnographic research at the point of recruitment before they agree to participate. Timings should be clear;
- Inform Market Research subjects at recruitment of any activities they will be asked to undertake;
- Use language that is understandable;
- Explain significant factors that could influence the person's willingness to participate (such as risks, discomfort, adverse effects, or limitations on confidentiality);
- Guard against unwarranted intrusion; so safeguards and the ability to end the observation quickly should be built in – the right to withdraw MUST be respected.

Constraints

7.10 There are a number of constraints upon how covert observational data may be collected and used:

- Where recordings for Market Research purposes are made in public areas e.g. in store, signs MUST be displayed indicating:
  - Who is recording;
  - Purpose of recording;
  - Means of contact – phone number.
- Signage should be displayed with some prominence in a large and readable typeface.
- Cameras MUST be sited so that they monitor only the intended areas.

For further information please see MRS Guidelines for Qualitative Research Including observational, ethnographic and deliberative research and ESOMAR Passive Data Collection, Observation and Recording[28].

Online & Mobile Market Research

Definitions

7.11 Online or internet research refers to research in which a Market Research subject or researcher is involved in any of the following:

- Completing research documentation online regardless of access route;
- Downloading research documentation from a server and returning it by email;
- Receiving research documentation incorporated into an email and returning by email;
- Participating in an online qualitative interview or discussion;
- Taking part in a measurement system which tracks web usage;
- Participating in an online message board;
- Collecting information from social media;
- Any other collection of data in the online environment for the purpose of Market Research.

7.12 Mobile Market Research (sometimes referred to as eResearch) involves the collection of information by mobile device (mobile phones, tablets and other similar mobile computing devices) for Market Research purposes.

These guidelines apply to Market Research carried out on mobile phones or devices and to browser based or downloaded applications, passive and active data collection.

7.13 An online 'access panel' is defined as a sample of potential Market Research subjects willing to receive invitations to participate (if selected) in future online interviews. Further guidance for research suppliers setting up and managing online panels are available from ESOMAR[29].

7.14 A Market Research subject's email address or other personal identifiers (e.g. screen or user name or device identifier) is personal data where it refers to an individual and therefore needs to be protected in the same way as other identifiers. A person's digital image is personally identifiable data. Geo–location data may be considered personal data too.

7.14.1 **In Germany** Guideline for Online Surveys applies and should be strictly followed. It is available here https://www.adm–ev.de/wp–content/uploads/2018/11/RL08_E_Online_2007_%C3%9CBERGANG.pdf

Informed Consent

7.15 If relying on informed consent you must provide an easy way for Market Research subjects to supply and withdraw it.

7.16 Market Research subject consent is required for the installation and use of software such as an app and Market Research subjects MUST be made aware of its purpose, the type of data it collects and its impact on functioning or performance such as degradation of battery life. For further details see *ESOMAR's Guideline for Conducting Mobile Market Research*.

28 https://www.mrs.org.uk/pdf/2014–09–01%20Qualitative%20Research%20Guidelines.pdf and http://www.esomar.org/uploads/public/knowledge–and–standards/codes–and–guidelines/ESOMAR_Cod es–and–Guidelines_Passive_Data_Collection–Observation–and–Recording.pdf

29 https://www.esomar.org/uploads/public/knowledge–and–standards/codes–and–guidelines/ESOMAR_2 6–Questions–To–Help–Research–Buyers–Of–Online–Samples.pdf These cover panel recruitment, project management, monitoring, maintenance and data protection issues

Privacy and Data Protection

7.17 Researchers MUST post a privacy policy statement, sometimes referred to as a privacy notice. The statement should be easy to find, easy to use and understand, including by children when appropriate.

7.18 Links to data protection; privacy policy or cookie consent statements MUST be given at the start of the Market Research. This will ensure that should Market Research subjects fail to complete the exercise for any reason their rights are protected.

7.19 If a repeat or follow–up survey is intended, a lawful basis for storage of their contact data e.g. consent is needed. The Market Research subjects MUST be able to refuse further participation in the survey via a suitable option and to refuse further contact by email in connection with the survey.

7.20 When emails are sent in batches, Market Research subjects' email addresses MUST be kept confidential, so for instance blind copying should be used.

Market Research Subject Costs

7.21 Market Research subjects should be alerted to any costs they may incur e.g. online charges and recompensed appropriately for these.

Researcher or Agency Contact Details

7.22 Market Research subjects should be told of the researcher's identity and given contact details. They should also be given the opportunity to find out more about the research agency carrying out the study, by giving them the name of the organisation together with an address, a corresponding hyperlink is recommended. When working overtly in social media sites, researchers should also provide contact details.

Protecting Personal and Company Data

7.23 Researchers MUST use adequate technological and organisational measures to protect personal data when collected, transmitted or stored on websites or servers.

7.24 Clients should be made aware of the potential risks of using confidential information in online or mobile surveys (e.g. within product descriptions). Agencies should be required to implement strict security procedures. Confidential information even if protected by non–disclosure agreements is easily printed/stored/forwarded and practically impossible to remove from circulation.

Cookies

7.25 In accordance with the European ePrivacy Directive, you must inform your website users that you place cookies on your website and why, as well as provide clear description of the data collected.

Interview Duration

7.26 Market Research subjects should be told the length of time the questionnaire is likely to take to complete under normal circumstances (e.g. assuming connection is maintained and standard connection speed).

Disclosing List Sources from Website Registration Databases

7.27 Where lists (including client–supplied lists) are used for sample selection, the source of the list MUST be disclosed. Where these are derived from website registration databases, researchers MUST check that registration was voluntary, and that the data are current.

Use of Unsolicited Emails for Recruitment

7.28 Researchers should avoid intruding unnecessarily on the privacy of Market Research subjects. ESOMAR advises that unsolicited e–mail approaches to potential Market Research subjects should not be made even in countries where this is permitted by law unless individuals have a reasonable expectation that they may be contacted for research. ESOMAR provides a 'Summary of regulations covering unsolicited contacts (business to consumer[30])' May 2013

When receiving email lists agencies should verify that individuals listed have a reasonable expectation, they will be contacted for Market Research purposes.

7.28.1 **In Mexico**, unsolicited email must not be sent unless a previous relationship exists, and the recipient is aware and agrees to that use in the sender's privacy disclaimer.

7.28.2 **In the Netherlands** article 11.7 of the Telecommunications Act (Telecommunicatie wet) requires prior consent from individuals to be contacted via their email addresses for commercial (charitable or idealistic) purposes. When an e–mail address is used for sending invitations for research, or for sending a survey, this is considered not to be commercial (charitable or idealistic) purposes, but purely for research, information gathering, and therefor prior consent is not required. If, however, under the pretence of Market Research the intention is to sell something, this exception does not apply.

7.28.3 **In the USA** the Federal CAN SPAM Act and INSIGHT ASSOCIATION's mandatory Code of Standards requires prior consent from individuals to be contacted via their email addresses. INSIGHT ASSOCIATION's Code requires research organisations to verify that individuals contacted for research by email or text message have a reasonable expectation that they will receive email or text message contact for research (and provide further detail upon what constitutes 'reasonable expectation').

7.28.4 **In the UK** Market Research emails are not defined as commercial communications within the 2011 Amended Privacy and Electronic Communications Regulations. Consequently, clients can forward customer email addresses to agencies (for recruitment purposes), unless the client has included Market Research in their standard data protection opt out policy

Identification of the Client

7.29 Data protection law requires you to identify data controller(s), recipients of personal data and the source of the personal data (if it wasn't obtained directly from the individual). Therefore, the end client company needs to be identified if they any one of these three criteria.

Use of Apps

The AMSRS (Australia), the MARKET RESEARCH SOCIETY (UK) and INSIGHT ASSOCIATION (USA) also provide the following guidelines, drawn from the Draft Mobile Research Guidelines August 2013:

https://www.mrs.org.uk/pdf/2013–08–30%20Draft%20AMSRS%20CASRO%20MRS%20Mobile%20Research%20Guidelines.pdf

7.30 Researchers MUST NOT:

- Install software that modifies the mobile settings beyond what is necessary to conduct research;
- Install software that knowingly causes conflicts with the operating system or cause other installed software to behave erratically or in unexpected ways;
- Install software that is hidden within other software that may be downloaded or that is difficult to uninstall;
- Install software that delivers advertising content, with the exception of software for the purpose of legitimate advertising research;
- Install upgrades to software without notifying users and giving the participant the opportunity to opt out;
- Install software that inordinately drains battery life;
- Install software that causes any costs to the participant that aren't reimbursed by the research organisation;

30 http://www.esomar.org/uploads/professional_standards/guidelines/ESOMAR–Codes&Guidelines–Legis lative–issues–unsolicited–contacts.pdf

- Install or utilise geolocation tracking software that would compromise the participant or their personal data;
- Create a risk of exposing personal data during data transmission or storage;
- Change the nature of any identification and tracking technologies without notifying the user;
- Fail to notify the user of privacy practice changes relating to upgrades to the software; or
- Collect identifiable data that may be used by the app provider for non–research purposes; or
- Extract information from the mobile device or phone unless this information is part of the purpose of the study (and informed consent is obtained).

Using Identification and Tracking Technologies/Software

7.31 Market Research subjects MUST always be told at the first opportunity when software is being used to collect information about them, they MUST also be told:

- Why it/they are to be used;
- If the data subject's information is to be shared;
- That they can turn them off or remove them.

7.32 Consent for downloading software to be used for Market Research purpose should be sought and a means provided to address questions.

ESOMAR provides example disclosure statements within its Guidelines for Online Research 2011 and details a series of 15 'Unacceptable Practices' that researchers must forbid or prevent. https://www.esomar.org/what–we–do/code–guidelines/esomargrbn–online–research–guideline

7.32.1 **In Germany** websites that use analytics tools MUST give users the chance to opt out.

7.32.2 **For the USA** INSIGHT ASSOCIATION provides detailed guidelines with regard to the use of active agent technology within its Code of Standards and Ethics.

Online Access Panels

7.33 Panel members MUST be made aware that they are members of a panel and should be reminded of this at regular intervals. Access panels are a sample database of potential Market Research subjects who declare that they are willing to receive invitations to participate in future online interviews. At recruitment potential panel members MUST be told that their personal data may be stored for further Market Research and there must be a lawful basis for this in place.

ESOMAR provides a series of guidelines on internet access panels, covering panel recruitment, management, monitoring, maintenance and privacy/data protection, and a battery of 26 Questions to help research buyers. More details can be found within these guidelines and the question battery can be found at ESOMAR Guideline for Online Research Aug 2011.

ESOMAR are also developing joint guidelines with the GRBN for Online Sample Quality which provide guidance on the operational requirements for providing online samples for market, research.

https://www.esomar.org/uploads/public/knowledge–and–standards/codes–and–guidelines/ESOMAR–GRBN–draft–Online–Sample–Quality–Guideline–April–2014.pdf

Social Media

Definition

7.34 Social media is defined by ESOMAR as internet–based platforms and technologies that permit users "interaction and/or facilitate the creation and exchange of user generated content."

Widely used examples include:

- Online forums/discussions, communities, blogs, social networks (e.g. Facebook)
- Video/photo sharing (e.g. YouTube)
- Multi–person/group communication and/or collaboration platforms (e.g. Twitter).

7.34.1 **In the UK** as with all forms of MR, appropriate AE/PC/SRS reporting processes must be put into place for MR using social media. In addition to the ABPI/BHBIA's Guidance notes on collecting adverse events, product complaints and special reporting situations during market research it may be helpful to consult the ABPI's Guidance notes on the management of adverse events and product complaints from digital media available online: http://www.abpi.org.uk/publications/safety–data–websites

Accessing Social Media Content including Website Terms and Conditions

7.35 You must have legal grounds for accessing content on social media, these are likely to be either consent or legitimate interests. When conducting social media Market Research, researchers are bound by the terms and conditions attached to access of the online services. Many service providers include intellectual property rights clauses that prohibit copying of material without consent. Researchers should ensure that they abide by the terms and conditions attached to use of site content. However, if consent for listening/scraping is not given, researchers can read and précis the content.

Anonymising Quotations

7.36 Care should be taken to ensure that anonymous quotations are indeed anonymous and cannot be traced back to reveal their original source.

Passive Market Research i.e. digital listening, scraping

7.37 Without the contributor's consent (obtained as part of the terms of use or directly) or another lawful basis only anonymised data can be reported. Anonymised data should not reveal any personally identifiable information.

7.38 No attempt should be made to identify contributors. ESOMAR states that this MUST be a contractual obligation if the data is passed on to the client or another researcher. If a contributor's comments are to be made public (i.e. cannot be covered by contractual obligations) and the contributor is identifiable, their consent should be sought or the comment disguised or 'masked' appropriately.

7.39 Quotations containing personal data can only be provided to the client if you have a lawful basis for this e.g. the contributor has given their consent for this and it has been made clear that they will not be subject to promotion as a result of this.

7.39.1 **In Germany**, Market Research subject identity must remain anonymous and Market Research subjects cannot be asked to waive their right to confidentiality

7.40 In 'private' SM spaces (ones in which users would expect their comments to be private), researchers should seek and gain the consent of contributors to listen in/scrape comments, other lawful bases are unlikely to be appropriate in these circumstances. Comments given to clients MUST be masked unless the contributor gives consent for their comments to be passed on verbatim. This assumes the terms and conditions have not given explicit site owner and site user consent for listening in/scraping.

7.40.1 **In Germany** it should be remembered that local Market Research guidelines prohibit asking Market Research subject/contributor consent to pass their personal data to the client company.

Active Market Research i.e. engaging with participants

7.41 Consent from the site/service owners and contributors/users MUST be given.

7.42 Researchers MUST declare their presence; they MUST NOT represent themselves as anything other than Market Researchers.

7.43 Contributors should be told the identity of the research organisation, purpose of the Market Research, what sort of data will be collected, how their comments will be used and who will have access to it. If processing personal data, you must meet data protection requirements.

7.44 Contributors **should** be provided with contact information for the researcher or research agency. If you are processing personal data you must identify data controller(s), recipients of personal data and the source of the personal data (if it wasn't obtained directly from the individual).

7.45 Researchers should publish a privacy policy/notice on their website.

7.46 Online space created specifically for Market Research such as MROCs should fulfil the following criteria:

- Participants MUST be aware of its function and the use to which their contributions might be put and that the data will be shared with the client;
- Any rules for interacting MUST be available;
- Site privacy policy MUST be available;
- The personal identity of participants MUST be protected.

Adverse Event Reporting

7.47 Adverse event reporting requirements are the same when Market Researchers use social media as a source of Market Research data as any other Market Research medium such as face to face interviews. Marketing authorisation holders and their contracted agents have an obligation to collect and follow–up on the adverse events and product complaints associated with their medicinal products. This applies to public and private sites, passive and active approaches and to company sponsored and non–company sponsored websites.

If a company chooses to listen–in to or 'scrape' from non–company sponsored sites, whether public or private (with consent) it is recommended that the listened to pages should be monitored for adverse events for the period of the listening–in activity only. There is no obligation for researchers to monitor non–company sponsored sites routinely for adverse events if they are not being used for a Market Research purpose.

8. MARKET RESEARCH SUBJECTS' RIGHTS BY MARKET RESEARCH SUBJECT TYPE

Patients

8.1 When researching existing or future potential medical treatments with patients, care should be taken not to:

- Raise unfounded hopes of treatment of specific medical problems;
- Mislead Market Research subjects with regard to the safety of a product;
- Encourage members of the public/patients to ask their doctor to prescribe a product;
- Offer advice on the specific therapy area under discussion.

It is also important to remember that personal data that includes data about an individual's health is special category of personal data and explicit consent is required to process it; and particular care should be taken when collecting, transferring or storing it as it constitutes a higher risk.

8.1.1 **In Finland and Sweden** interpretation of national legislation on data protection and patient anonymity appears to suggest that direct use of patient records for Market Research is difficult, even if the data is anonymised because of concerns about indirect identification, unless written consent from the patient has been secured. It is acceptable for physicians to complete patient record forms from memory although great care must be taken to ensure that the patient cannot be identified directly or indirectly. EphMRA strongly advises that the sponsoring pharmaceutical company's legal department seek local advice on the matter.

Simulated Consultations

8.2 Simulated consultations between a patient and a healthcare professional (known or unknown to each other) are a legitimate research approach however they should be conducted with great care because they may lead to misunderstanding with the patient. It is important that participating patients are fully aware of the nature of the research and that the consultation is a simulation and not a substitute for a normal consultation.

8.3 There is no restriction upon the use of protected health information if it has been de–identified. There are two ways to de–identify data.

1. The first method is to remove all identifiers such as:
   - Names;
   - All geographic data, including street address, city, county, part or all of the postal code;
   - Elements of dates (except year) directly related to an individual, including birth date, admission date, discharge date, date of death; and identifying ages e.g. those over 89;
   - Telephone numbers;
   - Fax numbers;
   - Electronic mail addresses;
   - Social security numbers;
   - Medical record numbers;
   - Health plan numbers;
   - Account numbers;
   - Certificate/license numbers;
   - Vehicle identifiers and serial numbers, including license plate numbers;
   - Device identifiers and serial numbers;
   - Web Universal Resource Locators (URLs);
   - Internet Protocol (IP) address numbers;
   - Biometric identifiers, including finger and voice prints;
   - Full face photographic images and any comparable images; and
   - Any other unique identifying number, characteristic, or code.
2. The second option is to have a qualified statistician determine that the risk is very small that the information could be used to identify the individual.

   https://www.hhs.gov/hipaa/for–professionals/privacy/special–topics/de–identification/index.htm

Vulnerable Market Research subjects

Definition

8.4 Vulnerable Market Research subjects are those who for whatever reason could be more susceptible than normal to physical or mental stress induced by the research process. Patients may well prove to be vulnerable Market Research subjects because of their age, physical or mental health. A vulnerable Market Research subject could be someone who is HIV positive or has cancer, a psychiatric illness or is physically handicapped.

What to Consider When Interviewing Vulnerable Patients

8.5 If the Market Research subjects are considered vulnerable, then the following questions should be considered:

- Is the Market Research justifiable?
- Is the nature of interview/tasks involved appropriate?
- Should a carer be present or on hand if required?
- Is additional time or the provision of breaks needed?

8.6 When a potentially sensitive issue has been discussed with a vulnerable Market Research subject, members may provide information or relevant helpline information.

8.6.1 **In the UK** the Mental Capacity Act passed in April 2005 enforced in 2007 provides codes of conduct on how vulnerable adults who lack the capacity to consent for themselves should be consented into research. The Act allows for another adult such as a next of kin or legal representative to consent on their behalf, the patient's doctor cannot give this consent alone. However, there is an onus on the researcher to withdraw the Market Research subject from the study if they show any sign of being unhappy or distressed by being included in the study.

Children and Young People

Definitions

8.7 When conducting research with children or young adults, ESOMAR advises that in the absence of a national definition, 'child' is a minor 12 years old or less and a 'young person' is 13 to 17 years of age.

8.7.1 **In Canada**, a child is to be defined as under the age of 14, a young person as aged 14–17.

8.7.2 **In Mexico** all those under 18 are considered children.

8.7.3 **In the UK** MRS Code of Conduct defines a child as a person under the age of 16 and 'young people' refers to those aged 16 and 17 years.

8.7.4 **In the USA**, the Children's Online Privacy Protection Act (COPPA) requires verifiable parental or the legal guardian's consent for interviewing children below the age of 13 years. If you are relying on consent as your lawful basis for processing personal data, when offering online services directly to a child, only children aged 13 or over are able provide their own consent.

8.7.5 **In South Korea** If the data subject is under the age of 14, the consent must be obtained from the legal guardian.

Consents Required

8.8 Consent from the responsible adult i.e. an adult responsible for the child's safety and welfare at the time of the research, is required to ask the child whether they will participate. Consent of a parent or responsible adult MUST be obtained before interviewing a child under 15 in the following circumstances:

- In home/at home (face–to–face and telephone interviewing);
- Group discussions/depth interviews;
- Postal questionnaires;
- Online questionnaires or email;
- Where interviewer and child are alone together;
- In public places such as in–street/in–store/central locations unless the child is 14 years or over, in which case interviews may take place without the consent of a parent or responsible adult.

8.8.1 **In Germany**, Children under the age of 11 years must be assumed in principle not to have this cognitive faculty. This means that recruiting and/or interviewing of children under the age of 11 years is not permissible in principle if the child is not accompanied by a legal representative, meaning that consent cannot be obtained. When interviewing children between 11 and 13 years it is the responsibility of the agency conducting the research either to have the interviewers discover the cognitive faculty or – to ease the burden on the interviewer – to assume in general that this age group does not possess the cognitive faculty and therefore the consent of a legal representative is required. In making such a decision, the research topic may also be relevant. Irrespective of the alternative "consent of a legal representative" or "cognitive faculty of the child /adolescent" interviews with minors under the age of 14 years should not be conducted without the knowledge of an adult present in the home. This includes that the interviewer should not enter a home if, apart from the child /adolescent under the age of 14 years, no adult is present at that time. Depending on the research subject for population samples different age limits are relevant. For adolescents in the age group of 14 to 17 years the necessary cognitive faculty can be assumed in principle. If no legal representative is present when interviewing adolescents, the "Declaration on Data Protection" shall be handed over to the adolescent.

8.8.2 **In Mexico**, written consent from the responsible adult must be obtained for all Market Research with Market Research subjects under 18 years of age.

8.8.3 **In the UK** in certain circumstances the adult consent may be waived but only with permission from the MRS's Standards Board.

8.9 Explicit consent from the child MUST also be given; the child MUST have their own opportunity to agree or decline to participate. When online research is carried out, a notice to children informing them of the requirement for consent MUST be shown at the point where personal information is requested.

8.10 Personal information relating to other people MUST NOT be collected from children unless it is to be used to gain consent from a parent/responsible adult. Where consent is being sought, it may be preferable for some classification questions to be asked of the parent/responsible adult, rather than the child/young person.

8.11 Details of the person giving consent (name and role) MUST be recorded.

8.12 The responsible adult MUST be made aware of any observation or recording.

Online Market Research with Children

8.13 EphMRA recommends that online research is not conducted with children under the age of 14.

8.14 For online research with children Market Research subjects should be asked to give their age before any other personal information is requested. If the age given is under 15, the child MUST be excluded from giving further personal information until the appropriate consent from the responsible adult has been obtained and verified.

8.14.1 **In the USA**, researchers MUST abide by the Children's Online Privacy Protection Act (COPPA). This federal ruling applies to the online collection of personal information from children under 13. It details what a website operator MUST include in a privacy policy, when and how to seek verifiable consent from a parent and what responsibilities an operator has to protect children's privacy and safety online[31].

8.15 A notice to the parent/responsible adult should be placed on the website or sent via email asking for their consent for the child to participate in online Market Research. ESOMAR provide guidelines upon the recommended content of such a notice. See ESOMAR Online Research Guidelines 2011.

Role of the Responsible Adult

8.16 Consider the necessity for the presence of a parent/guardian during fieldwork. It is recommended that when interviewing a child in their own home, a parent/responsible adult is present, not necessarily in the room but in the house. If a child or the responsible adult asks for an adult to be present, this request should be respected.

8.17 The researcher should ensure that the responsible adult has full details of the research venue, name of moderator, finishing time, etc.

Researchers' Responsibilities

8.18 No study can ask a child to do something illegal for their age.

8.19 Language on questionnaires should be suitable for the age group.

8.20 Refreshments provided should be suitable for the age group and care should be taken to avoid including anything that is known to cause allergic reactions.

8.20.1 The researcher should take responsibility for safely handing over the child/young person after an interview or ensuring that arrangements for them to get home safely are in place.

8.20.2 **In Canada**, MRIA affiliated researchers must take into account the degree of maturity of the child or young person involved when considering what subjects may or may not be safely dealt with in an interview.

31 http://business.ftc.gov/documents/Complying-with-COPPA-Frequently-Asked-Questions

Incentives

8.21 Where incentives are used, they should be suitable and acceptable for the age of the child/young person and fitting for the task required.

Product Testing

8.22 If a child is going to be asked to test a product, the responsible person should be allowed to see this and (if they wish) to try it themselves.

8.23 If children/young people are to be asked to take part in any form of product testing, researchers should take special care to ensure that the products are safe to handle or consume and that the child/young person does not suffer from any relevant allergy. EphMRA recommends that active medicines are not used in Market Research with children.

Criminal Record Checks for Interviewers

8.24 Criminal record checks for interviewers may be necessary in some circumstances but it is not necessary for all researchers.

Opinion Leaders, Clinical Trial Investigators and Advisory Board Members

8.25 When recruiting Market Research subjects that have a pre–existing relationship with the company e.g. clinical investigators, opinion leaders or advisory board members, it is acceptable for the initial invitation to participate in the Market Research to come from the client company. However, their decision to participate or not MUST remain confidential i.e. the client company MUST NOT know who did or did not participate.

8.26 A senior member of the marketing or clinical department may provide the following information in writing – an outline of the:

- Company's aims in undertaking Market Research (e.g. to obtain feedback on the clinical performance of a new drug in trials);
- Reasons why the Market Research subject has been chosen (personal experience of drug, expertise in therapeutic field);
- Credentials of the researcher/agency undertaking the study and names/contact details of personnel who will conduct the interview;
- Procedure for selecting any trial patients for inclusion in the study (via records or interviews) if required.

However, it should be noted that in some circumstances or cultures this may be misinterpreted as or considered disguised promotion. So, this approach should be used with great care.

Physicians and Other Healthcare Professionals

8.26.1 In some countries the professional associations or employers (for/of salaried healthcare professionals) may need to give approval for their members/employees to take part in Market Research studies.

Payers and Influencers

8.26.2 Given the potentially sensitive nature of discussions with payers and influencers, care should be taken to ensure that their professional role is respected, and they are not pressured to impart inappropriate information.

Please note the guidelines provided within Section 5, K7 Sensitive Topics.

9. PAYERS AND INFLUENCERS

9.1 Breaches of the Code of Conduct and complaints will be investigated in the first instance by EphMRA's Ethics Group, and if necessary, concerns/complaints upheld by EphMRA may then be referred to the appropriate regulatory body, following which disciplinary measures may be taken by these organisations.

9.2 If the relevant Data Protection legislation is breached, action can be taken by the appropriate Data Protection Authority in the relevant country e.g. the Information Commissioner's Office in the UK. For a list of European Data Protection Authorities see – https://edpb.europa.eu/about–edpb/board/members_en

ANNEXES

Annex 1 ADVERSE EVENT REPORTING

Update: 2020

EphMRA Adverse Event Reporting (AER) Guidelines

These guidelines provide the principle requirements of Pharmacovigilance (PV) reporting for individuals or organisations involved in market research (MR) activities within the healthcare industry. This includes those working for a Marketing Authorisation Holder (MAH), Market Research Organisation (MRA) or other organisations involved in MR activities. It applies to employees and contractors working with or for a MAH, MRA or other organisations engaged in MR.

The principles relate to global PV requirements with particular reference to the European Medicines Agency's (EMA) Guideline on Good Pharmacovigilance practices (GVP), Module VI for the 'Collection, management and submission of reports of suspected adverse reactions to medicinal products[1]'.

(ref. EMA 28 July 2017EMA/873138/2011 updated August 2017, Rev 2).

EphMRA Members' Responsibilities

- MRAs and MAH should comply with regulatory Pharmacovigilance requirements with consideration of local codes and regulations including data protection.

This applies to the MRA, including subcontractors, fieldwork agencies, analysts, interviewers, and MAH functions, e.g. global/regional/local market researchers, commercial / marketing, medical, health economics & outcomes research (HEOR), Market Access and others involved in MR activities.

1. INTRODUCTION

Pharmacovigilance

Pharmacovigilance (PV) is '*the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine–related problem*'[2].

Before a regulator authorises a medicine for use, evidence on the safety and efficacy is limited to clinical trials conducted in defined patient population(s) and for relatively short time periods. After regulatory authorisation the medicine may be used in a broader patient population and for longer time periods where new or an increase in known side effects may appear.

The Marketing Authorisation Holder (MAH) is responsible for monitoring, collecting and reporting suspected adverse reactions associated with medicinal products for human use including prescription and non–prescription, e.g. over–the–counter (OTC) products, and managing the safety of all its medicines during their use in healthcare practice.

1 https://www.ema.europa.eu/en/documents/regulatory–procedural–guideline/guideline–good–pharmacovigilance–p ractices–gvp–module–vi–collection–management–submission–reports_en.pdf (accessed 05/02/2020)

2 The European Medicines website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000258.jsp&mid=WC0b01ac0580b18c76 (accessed 05/02/2020)

Basis of Guidelines

EphMRA's Adverse Event Reporting Guidelines detail the scope of the responsibilities and requirements of the process for Adverse Event reporting for market research activities.

The term 'Adverse Event' is used as an umbrella term within these guidelines. An Adverse Event (AE) refers to an untoward response to a medicinal product and which does not necessarily have to have a causal relationship with this treatment.

Where it is reasonable to assume a causal relationship with a medicinal product this is referred to as an Adverse Reaction (AR). The MAH PV will assess to determine if there might be a causal relationship or not for the purpose of AE reporting. It is not the role for market research to do this and as such the term AE is used in the EphMRA AE guidelines

2. ADVERSE EVENT – DEFINITIONS

Adverse Event (AE)

An Adverse Event is an unintended and unfavourable response to a medicine, whether or not considered to be related to the medicine (i.e. causal relationship).

Special Reporting Situations (SRS)

Situations where a medicine is used outside of the marketing authorisation, including:

- **Overdose or Lower dose**: use per administration or cumulatively above the recommended authorised maximum dose.
- **Off–label use**: intentionally used for a purpose not within the intended use or authorisation for the medicine
- **Misuse**: intentional and inappropriate use outside of the marketing authorisation for the medicine
- **Abuse**: persistent or sporadic, intentional excessive use of a medicine accompanied by harmful physical or psychological effects [DIR Art 1(16)].
- **Occupational exposure**: contact with a medicine as a result of professional or non–professional occupation, e.g. splitting or cutting capsules and tablets.
- **Medication error**: includes dispensing errors, accidental exposure, maladministration
- **Lack of, or unexpected, therapeutic effect**: where an additional benefit not previously known is reported.
- **Drug of drug–food interactions**: effectiveness or toxicity of one medication is altered by the administration of another medicine(s), foods interfering with medication, e.g. grapefruit or grapefruit juice with some statins and other medicines.

Note: MAH and MRA to agree additional SRSs, e.g. hospitalisation, pregnancy, breast feeding, transmission of infective agent, etc.

Product Complaint (PC)

Includes suspected failure of a medicine, damaged, missing, incorrect strength or colour of medicine, damaged packaging, missing patient information leaflet, broken or damaged needle or syringe, counterfeit medicine, etc.

3. RESPONSIBILITIES FOR AE REPORTING FOR MARKET RESEARCH STUDIES

Who is responsible?

- **All MAH personnel** (e.g. market research, business intelligence/information, marketing, etc) and including representatives and contractors
- **All Market Research Agency (MRA) personnel** working on behalf of the MAH, including the agency, sub–contractors, recruiters and fieldwork, interviewers, analysts, etc
- MRAs should have a contract in place with all their suppliers on the required AE reporting process.

Responsibilities and processes

- The MAH is primarily responsible for compliance with global, regional and local PV regulations and for assessing whether MR studies may generate AEs, SRSs or PCs.

- Where a MAH engages an MRA to provide MR services, explicit procedures and detailed agreements for AE reporting should be put in place, i.e. contractual arrangements, to ensure the MAH can comply with regulatory requirements.
- The MAH's PV is responsible for managing reporting of the Individual Case Safety Report (ICSR), recording incomplete AE reports (not a valid ICSR), and all associated follow–up actions, if appropriate.
- The MRA can only provide the contact details of the patient or HCP to the MAH if there is a lawful basis under data protection legislation for this.
- There are six bases for lawful consent (EU GDPR, 2016). Market research studies most commonly use the participant's* consent as a lawful basis for the transfer of personal data, but this is not the only option.
- If consent is used as the lawful basis for the transfer of personal data, this is a separate data processing operation and requires the participant's consent. This may be done at the end of the interview.
- Where the MRA subcontracts its MR obligations to a third party, e.g. a fieldwork agency, it should ensure the subcontractor undertakes AE reporting to comply with all legal, regulatory and contractual requirements in general.
- Co–promotion or co–marketing situation: the MRA should agree with the commissioning company the process for AE reporting.

Note: 'Data subject' is used in the EphMRA guidance in line with GDPR terminology rather than participant* or research subject.

Responsibilities to Data subjects

All data subjects, whether HCPs or patients, should be informed at appropriate times (e.g. at recruitment, start of interview), of the requirement for MAH's to report AEs arising during MR.

Disclosure of Transfer of Value

- In general disclosure requirements under European Federation of Pharmaceutical Industries and Associations (EFPIA) code, 2019[3] and the US Physicians Payment Sunshine Act, 2010[4] relating to Transfer of Value (ToV) do not require MRAs to identify the names of the HCPs who report AEs during MR studies.
- These are considered as solicited AE reports. The HCP's personal data are provided to the MAH's PV for the purpose of AE reporting only and is dependent on the HCP's consent to pass the information.

4. AE REPORTING REQUIREMENTS

- The MRA should agree the AE reporting requirements with the MAH at the start of MR but before recruitment and fieldwork starts.
- The MRA should also agree AE reporting requirements with the MAH associated with medical devices as these may differ compared to medicinal products.
- AEs for any medicines where the commissioning client holds the marketing authorisation need to be reported to the MAH's PV.
- AEs should be forwarded where the reporter uses either the company's brand or the generic name.
- The commissioning MAH can provide a list of the medicines for which they hold the marketing authorisation for the countries included in the study, including brand and generic names, to the MRA at the start of the MR.
- MRAs are not required to collect AEs cited for other companies' medicines, or report AEs cited in groups of drugs.
- Any type of AE, no matter the level of severity, should be reported by the MRA.

When and how to complete AERs

The AER may be completed at the end of recruitment or the MR interview – there is no need to interrupt the interview to do this.

3 https://www.efpia.eu/media/413022/efpia–code–2019.pdf Transfers of Value (ToV), p8 (Direct, or indirect where the Member Company knows or can identify the Recipient who will benefit from the ToV

4 https://www.govinfo.gov/content/pkg/PLAW–111publ148/pdf/PLAW–111publ148.pdf (accessed 23/02/2020), SEC. 6002. PUBLIC LAW 111–148—MAR. 23, 2010 TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS.

Provide as much detail as possible to complete the information required for AE reporting (refer reporting criteria below), preferably completing it with the help of the reporter.

The MAH should provide contact details for the MRA (including sub–contractors, fieldwork) to forward AERs, i.e. email, fax number, other secure electronic method for the transfer of data. Note: Country level privacy rules for transfer of personal information should apply.

Quality Management and Training

The MAH and MRAs should have clear and comprehensive operating procedures in place for the collection, forwarding and management of Adverse Events.

PV training requirements including AER should be agreed between the MAH and MRA before the start of the MR (some differences between MAH's requirements).

PV training including AER must be undertaken to ensure all individuals directly involved understand the requirements and what actions is needed.

The MAH should supply their AER form, or the EphMRA AER template may be used (access to the electronic system can be arranged).

Categories of AE sources for market research studies

There are two types of AE reports in the post–authorisation phase: "*reports originating from unsolicited sources and those reported as solicited*."[5]

Usually AE reported during MR studies are solicited, but it's important to recognise those that arise as unsolicited, spontaneous AEs.

- **Solicited**: includes AEs "*derived from organised data collection systems, including surveys of patients or healthcare professionals*"[6], e.g. personal/telephone/web–based interviews, surveys (paper, online, etc).
- **Unsolicited**: "*not related to any organised data collection systems*"[7] e.g. syndicated studies, social media/ digital listening (EMA classify as internet/digital media as unsolicited spontaneous).

Solicited and unsolicited AEs during MR studies with healthcare professional and / or consumers (refer definitions below) should be reported to the MAH's PV.

Primary sources of AEs: Healthcare professional and Consumer

Healthcare professional' (HCP): "*defined as a medically qualified person, such as a physician, dentist, pharmacist, nurse, coroner or as otherwise specified by local regulations*" [8]

Consumer: "*is defined as a person who is not a healthcare professional such as a patient, lawyer, friend, relative of a patient or carer*".

NOTE: EphMRA guidelines use **patient** as the more familiar and most used term in the healthcare industry, rather than consumer. However, it is important to note AE reporting still applies other types of 'non–HCP' participating in MR studies, e.g. a relative, friend or carer of the patient.

AE reporting criteria

The MAH's PV is responsible for managing and reporting valid Individual Case Safety Reports (ICSR) of suspected ARs to the relevant regulatory authorities. Four minimum criteria are required for a valid ICSR (see below).

The MAH's PV is expected to follow–up AERs where information is missing.

The MAH should still record AERs within its PV system where the minimum criteria are missing incomplete or missing for on–going safety evaluation activities.

AE reporting requirements should include if AEs should be forwarded to the MAH where there is incomplete or missing information, including on the four minimum criteria for valid ICSRs (requirements may differ between MAHs).

Minimum criteria for valid ICSRs

a. One or more identifiable reporter
b. Identifiable patient or group of patients
c. One or more suspected medicinal product
d. Suspected Adverse Event

5 EMA GVP, Module VI (Rev 2), EMA/87138/2011, Section VI.B.1. Collection of individual safety reports

6 EMA GVP, Module VI (Rev 2), EMA/87138/2011, Section VI.B.1.2. Solicited reports

7 EMA GVP, Module VI (Rev 2), EMA/87138/2011, Section VI.B.1.1.1. Unsolicited spontaneous reports

8 EMA GVP, Module VI (Rev 2), EMA/87138/2011, Section VI.A.1.4. Primary source, healthcare professional, consumer

- **Reporter**: characterised by their qualification, e.g. physician, pharmacist, or patient, name or initials, address (e.g. organisation, department, street, city, zip or postcode, country), email or telephone/ cell/mobile number.
- **Patient**: characterised by at least one of the following qualifying parameters: initials, data of birth, age/age group, or gender/sex.
- **Medicinal product**: medicine(s) where the commissioning client is the MAH (identified by brand or generic name).
- **Suspected Adverse Event**: includes serious and non–serious ARs, SRSs and PCs.

5. CONSENT AND AE REPORTING

Transfer to personal information in AERs

- The reporter's personal information, e.g. name, contact details, can only be forwarded to the MAH if the participant has provided consent or there is an alternative lawful basis in place[9] (refer GDPR, 2018).
- If consent is being used this must be provided before any data are transferred by the MRA to the MAH.
- Personal information must not be forwarded to the MAH if consent has not been given, although the subject can still take part in the MR. Under these circumstances the MRA must forward AEs as an anonymous report.
- When relying on consent for receiving and transferring personal data the sponsoring organisation could be named when personal information is obtained during MR (GDPR, 2018). For very specific studies, such as in–licensing or requirement of local codes, e.g. Denmark, the sponsor should not be identified. The respondent should provide their consent to participate on this basis (preferably documented) or decline.
- Consent for processing personal data for AE reporting purposes may be obtained at the start or end of the interview, as it is not essential for participating in MR.
- Information about an AE from a MR subject that relates to someone else's experience e.g. a patient's carer, relative or friend, it must be reported to the MAH without the personal details of the individual who experienced it as they have not consented to their details being forwarded.[10]

Patient 'special category' personal data

- Personal data that especially sensitivity is classed as 'special category' and requires additional security.
- Personal information (GDPR, 2018) includes race or ethnicity, sexual orientation, biometric or genetic data, religious beliefs, data on health problems as 'special category'.
- Patients must provide explicit consent if they are providing 'special category' personal data

MAH's PV AE Follow–up

- The MAH's PV may require to follow–up an AER with the patient's HCP. The MRA should ask the patient if they are willing to provide consent to include contact details for the relevant HCP in the AER, should further follow–up be required. the AE should still be forwarded to the MAH even if the patient does not give consent to include the HCP contact details.
- If the reporter has already notified the relevant authorities or MAH, AEs from MR should still be forwarded to the MAH.

The above refers to EU GDPR, 2018 regulation for guidance. The MRA should check applicable local and regional data protection requirements and agree with the MAH how this should be managed at the start of the MR. This should apply to the full data management process and documented (e.g. contract).

9 European Union (EU) Regulation (EU) 2016/679, (April 2016). General Data Protection Regulation. Came into force May 2018. https://eur–lex.europa.eu/legal–content/EN/TXT/?qid=1532348683434&uri=CELEX:02016R0679–20160504 (accessed 26/02/2020).

10 https://www.bhbia.org.uk/guidelines–and–legislation/AE–PC–SRS–Guidance (accessed 21/02/2020). BHBIA/ABPI (2018). Guidance notes on collecting adverse events, product complaints and special reporting situations during market research. August 2018, Section 4.2, p7

6. AE REPORTING TIMETABLE

- The regulatory clock starts – day zero – as soon as the MAH or MRA becomes aware of an AE in MR. The MAH is required to submit valid ICSRs as soon as possible but no later than 15 days calendar days.
- AEs must be forwarded by the MRA when they become aware of the information to the MAH's PV within the defined timeline agreed at the start of the study or contract, including missing/incomplete information if required.
- Awareness of an AE usually emerges during the MR interview/surveys, e.g. face–to–face, telephone, web–based, internet, mobile, Apps and other digital techniques, and at recruitment too.
- AEs must be the date when the respondent informed the MRA, e.g. completed interview/survey.

Any **potential variance for AE reporting timelines** should be agreed as part of AER requirements with the sponsoring client / MAH at the start of the MR.

7. REPORTING FORMATS

The two common AE reporting formats are:

- **AER Form**: collecting information during a MR interview, e.g. personal or group interviews. There is no need to interrupt the flow of the interview as the form can be completed at the end. Collect as many details as possible for minimum reporting criteria. The reporter can complete the form and sign. Otherwise the interviewer / agency fieldworker should complete the information and the reporter/subject sign the form before the AER is forwarded to the MAH.
- **Tabulation of aggregate data**: information provided in tables for review in aggregate or a large volume of AEs is anticipated, e.g. online surveys, particularly those collecting data on prescribing behaviour and potentially conjoint studies. The reporting format typically includes the number of MR subjects citing AEs but should be agreed with the MAH before the MR starts.

  Refer Appendix 1 – EphMRA AE Reporting Form template

Format of AE Tabulations

AER tabulations, e.g. structured or semi–structured surveys, should include:

- Number of MR subjects where an AE was cited
- Question base i.e. how many MR subjects answered the question

The format should be agreed with the MAH in advance of data processing

AER Reconciliation Process

Confirmation and/or reconciliation of AEs is a requirement upon completing a MR study.

A summary of all AEs identified during the MR is to be 'reconciled' with or checked against the individual AEs forwarded to the MAH's PV during the MR to ensure all AEs are accounted for. The MRA should agree the reconciliation process as some MAHs use a digital AER system.

The reconciliation form should be completed at the time period agreed at the start of the study or contract with the MAH's PV (e.g. end of fieldwork or study), even if no AEs were reported, i.e. report as "0" or "No AEs".

This applies to irrespective of whether information is collected using AE Report Form or tabulation of aggregate data.

The AER Reconciliation form should include for each country where MR was undertaken, the number of AEs identified (not just reported), summary by each AE of MR subject's ID, the medicine and the AE details.

Syndicated Studies

There is no legal responsibility for the MRA to forward AEs for syndicated studies. Syndicated primary market research studies are conducted by the MRA independently of any healthcare company (e.g. pharmaceutical, Biotech) and the results and data purchased by multiple clients.

Responsibility to collect AEs lies with the MAH that purchases the syndicated data.

The MAH should forward an AE identified from a purchased syndicated study to their PV. The MAH may however request the MRA to provide the data in an appropriate AER format.

Where confidential or proprietary questions are added to a syndicated survey by a MAH, the data from these questions must be treated in the same way as MR commissioned by the MAH, i.e. the MRA should forward AEs to the MAH's PV.

Longitudinal Patient Databases

Longitudinal patient databases e.g. GPRD (General Practice Research Database) are out of scope.

The Council for International Organisation of Medicinal Sciences (CIOMS) suggests that there is no obligation to search through such databases for individual AEs as this will give rise to spurious signals and conclusions however if they are found (deliberately or co–incidentally), they should be forwarded to the MAH.

Data from longitudinal patient databases are different to tabular AE summaries collected from MR as they have not arisen from a defined project and are for multiple users, not just acquired by an MAH for internal use (unlike commissioned MR).

AE reporting where social media is used in MR

- AE reporting requirements apply where social media, or social media associated techniques (e.g. online communities) is used as a source of MR data, i.e. treated as any other type MR study. The MAH and MRA should agree the process for collecting and reporting AEs associated with their medicinal products before the start of the study.
- This applies to public and private sites, passive and active approaches and to company sponsored and non–company sponsored websites, which should be monitored during fieldwork for AEs.
- If a company chooses to listen–in to or 'scrape' from non–company sponsored sites, whether public or private (with consent) it is recommended that the 'listened' to pages should be monitored for AEs for the period of the listening–in activity only.

There is no obligation for researchers to monitor non–company sponsored sites routinely for AEs if they are not being used for a MR purpose.

Who to Direct Queries To?

MRAs should direct queries relating to the AER process to the MAH's PV or MR contact as this is the most important source for guidance.

RESOURCES – WEBSITES:

- EphMRA website
- BHBIA website (UK)
- CMS's final rule on the Sunshine Act: www.federalregister.gov/ articles/2013/02/08/2013–02572/ medicare–medicaid–childrens– health–insurance–programs–transparency–reports–and– reporting–of
- European Union website
- European Medicines Agency
- https://www.cms.gov/OpenPayments/Downloads/Affordable–Care–Act–Section–6002–Final–Rule.pdf
- Physician Payment Sunshine Act Final Rule: Definitions, Policy and Medicine, Feb. 5, 2013: www. policymed.com/2013/02/physician– payment–sunshine–act–final–rule–definitions.html
- US Government Sunshine Act

Glossary of abbreviations

AE	Adverse Event
AER	Adverse Event Reporting
AR	Adverse Reaction
EMA	European Medicines Agency
EU	European Union
HCP	Healthcare Professional
ICSR	Individual Case Safety Report
MAH	Marketing Authorisation Holder
MR	Market Research

MRA	Market Research Agencies (including company and/or individuals conducting MR, including subcontractors, fieldwork analysts and interviewers)
PC	Product Complaint
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
SRS	Special Reporting Situations

EphMRA Adverse Event Reporting Form – TEMPLATE		
Market Research Agency and Project Details		
MR Agency name: Full Address:		
MR Agency contact telephone number:	Country Code: Number:	
MR Agency contact email		
Research Interviewer's name:	Title: First name: Surname:	
Research Interviewer's email address:		
Date aware of Adverse Event (*)		
Agency MR Project title/reference number		
MAH (**) project number / ID		
Respondent ID or AE number		
Patient Information		
No. of patients: *(Select 'multiple patients' only if individual identifying details are not available, otherwise please complete separate AE reports)*	Individual patient: Multiple patients: State number of patients if known:	
Availability of patient information	YES	NO
Age	YEARS	
Gender	FEMALE	MALE
	OTHER	PREFER NOT TO STATE
Drug and Event Information		
Drug name		
Indication drug prescribed		
Description of Adverse Event: *Please describe as fully as possible*		
Indication/condition for which drug prescribed		
Daily Dose of drug		NOT KNOW
Lot/batch number for drug		NOT KNOW
Frequency of dose of drug		NOT KNOW

Route of administration/form of drug		NOT KNOW	
Reported to local regulator?	YES	NO	DON'T KNOW
Does reporter think event might have been related to the drug?	YES	NO	DON'T KNOW
MR Subject/Reporter details			
MR subject / Reporter name	Title: First name: Surname:		
Reporter type (E.g. doctor, patient / consumer)			
Does the MR subject / Reporter agree to provide their contact details (e.g. address; email/phone optional)?			
	NOT AGREE TO PROVIDE		
Does the MR subject / Report agree to be contacted for follow up	YES, AGREE	NO, DO NOT AGREE	
	SIGNATURE		
Is the MR subject / Reporter a patient / consumer?	YES	NO	

* AE/PC/SRS = Adverse Event, Product Complaint and Special Report Situations
** MAH = Marketing Authorisation Holder

Sources

Legislation Supporting the Code of Conduct

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)
- EU Directive 2001/83/EC on the Community Code relating to Medicinal Products for Human Use
- EU Regulation 726/2004 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
- EU Council Directive 93/42/EEC concerning medical devices
- EU Directive on Privacy and Electronic Communications (2002/58/EC) 2003
- Health Insurance Portability and Accountability Act (HIPAA)

Australia

- The Research Society Code of Professional Behaviour
- Medicines Australia's Code of Conduct

Brazil

Law No. 13.709 of 14 August 2018, General Personal Data Protection Law.

Canada

- Code of Ethical Practices came into effect on January 1, 2020
- CRIC Public Opinion Research Standards and Disclosure Requirements

Denmark

- ENLI GUIDE on market research August 2019

Finland

Pharma Industry Finland Code of Ethics – Pharma Industry Finland 2019

France

- ASOCS Charte De Pratiques Loyales En Matière D'Etudes Des Opinions Et Comportements Dans Le Domaine De La Sante
- ASOCS, INFOSTAT & UDA Le Guide Des Relations Entre Laboratoires Et Societes D'Etudes
- Law No 2011–2012 on the Strengthening of Health Protection for Medicinal and Health Products (loi relative au renforcement de la sécurité sanitaire du medicament et des produits de santé
- Dispositions déontologiques professionnelles Applicables aux entreprises du médicament adhérentes du Leem December 2019

Germany

- Arbeitskreis Deutscher Markt– und Sozialforschungsinstitute e. V. (ADM), all guidelines available here https://www.adm–ev.de/standards–richtlinien/

Greece

- SFEE Code of Practice https://www.sfee.gr/wp–content/uploads/2015/04/triptixo.pdf
- Code of Ethics on the Promotion of Prescription–Only Medicinal Products & Disclosure of Transfers of Value by Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations as amended by the General Assembly of SFEE, on 16/3/2017 with effect from 01/06/2017

Japan

Act on the Protection of Personal Information 2017 subject to the "Every–Three–Year Review"

For the medical sector, the Ministry of Health, Labour and Welfare ('MHLW') has issued the following guidance:

- guidance for the appropriate handling of personal information by medical or care–related service providers (only available in Japanese here);

- guidance concerning safety management of medical information systems (only available in Japanese here);
- ethical guidelines concerning medical research targeting humans (only available in Japanese here);
- ethical guidelines concerning analysis and research of the human genome and genes (only available in Japanese here);
- guidelines concerning gene therapy clinical research (only available in Japanese here);

Japan Pharmaceutical Manufacturers Association (JPMA) Code of Practice

Japan Marketing Research Association Code of Conduct and relevant guidelines

Japan Medical Marketing Research Group and relevant guidelines

Italy

- ASSIRM, Code of Professional Ethics 2014
- Farmindustria, Code of Professional Conduct Oct 2016

Mexico

- AMAI: Estándar de Servicio para la Investigación de Mercados en Mexico – ESIMM V2.0 77
- LFPDPPP – Ley Federal de Protección de Datos Personales en Posesión de los Particulares
- Cofepris: Guías, Lineamientos y Requerimientos de Farmacovigilancia
- PROFECO Repep – Regístro Público para Evitar Publicidad
- CETIFARMA: Código de Ética y Transparencia de la Industria Farmacéutica

Netherlands

- Dutch innovative pharmaceutical sector Code January 1, 2020
- Code of Conduct for Pharmaceutical Advertising Jan 2017
- Concept Gedragscode Voor Marktonderzoek In De Healthcare Markt Draft Code of Conduct for Market Research in the Healthcare Market, Oct 2015
- MOA Code of Conduct for research and statistics (Gedragscode voor onderzoek en statistiek)
- Wet bescherming persoonsgegevens
- Telecommunicatie wet
- CGR Richtlijnen niet–WMO plichtig onderzoek
- Gedragscode Geneesmiddelenreclame
- CGR Uitwerking Normen Gunstbetoon
- Toelichting gedragsregels openbaarmaking financiële relaties,
- MOA guideline Publiceren over marktonderzoek
- MOA Onderzoekfilter

Denmark

- The Danish Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals 2014 Finland
- Pharma Industry Finland (PIF), Code of Ethics, 2017
- Market Research Association SMTL, Code of Ethics, 2011
- Market Research Association SMTL, Tietosuojakäytänne (Privacy Policy) 2003

Norway

- LMI – The Association of the Pharmaceutical Industry 2019

Poland

INFARMA Code of Good Practice

Sweden

- Ethical Rules for the Pharmaceutical Industry in Sweden Revised 16 April 2020, valid from 01 May 2020
- Svenska Marknadsundersökningsföretag (SMIF), Children and Youth Policy, Jan 2013
- Svenska Marknadsundersökningsföretag (SMIF), Tillämpningsregler PUL, Privacy Application Rules , 2010

Russia

AIPM Code of Practices 2019

Spain

- AEDEMO, Proteccion de Datos e Investigacion de Mercados 2007 Privacy & Market Research
- Farmaindustria, Code of Practice for the Pharmaceutical Industry 2016

South Korea

- Korea Pharmaceutical Manufacturers Association Code of Practices KPMA

Turkey

- AIFD Code of Good Promotional Practice 7th Edition Effective as of January 1st, 2019

UK

- Association of the British Pharmaceutical Industry (ABPI), Code of Practice 2016
- Association for Qualitative Research (AQR), Qualitative Research Recruitment 2002
- BHBIA Legal and Ethical Guidelines for Healthcare Market Research 6
- Market Research Society (MRS), Administering Incentives and Free Prize Draws July 2015
- MRS Best Practice Guide on research Participant Vulnerability Jan 2016
- MRS Code of Conduct 2014
- MRS Guidance on Collecting Data on Sex and Gender Jan 2016
- MRS Guidelines for Research with Children and Young People Sep 2014
- Data Protection & Research: Guidance for MRS Members and Company Partners 2018
- MRS Guidelines on the Privacy and Electronic Communications Regulations May 2011
- MRS Guidelines for Online Research Sep 2014
- Guide to Observers' Legal & Ethical Responsibilities Oct 2015
- MRS DRAFT Mobile Research Guidelines Aug 2013
- MRS Online data Collection and Privacy Discussion Paper Jul 2011
- MRS Online data Collection and Privacy Response to Submissions Apr 2012
- MRS Qualitative Research Guidelines including Observational and Ethnographic and deliberative Research Sep 2014
- MRS Questionnaire Design Guidelines Sep 2014
- MRS Use of Predictive Diallers Mar 2017
- MRS Using Research Techniques for Non–Research Purposes Nov 2010
- Office of Information Commissioner (ICO), Guide to Data Protection

Europe

- European Federation of Pharmaceutical Industries and Associations (EFPIA) Code on the Promotion of Prescription–Only Medicines to, and Interactions with, Healthcare Professionals 2014
- EFPIA Code on Disclosure Of Transfers Of Value From Pharmaceutical Companies To Healthcare Professionals And Healthcare Organisations 2014
- European Society for Opinion and Marketing Research (ESOMAR), Online Research Guideline, 2015
- ESOMAR Guideline for Conducting Mobile Market Research Oct 2012
- ESOMAR Guideline on Social Media Research Jun 2011

- ESOMAR Guidelines on the Mutual Rights and Responsibilities of Researchers and Clients Oct 2010
- ESOMAR How to Commission Research 2009
- ICC/ESOMAR International Code on Market, Opinion and Social Research and Data Analytics 2017
- ESOMAR Interviewing Children and Young People 2009
- ESOMAR Distinguishing Market Research from Other Data Collection Activities Mar 2009
- ESOMAR Passive Data Collection, Observation and Recording Feb 2009

South Korea

- South Korea Research–based Pharmaceutical Industry Association (KRPIA) Fair Competition Code 2014

USA

- CODE OF STANDARDS AND ETHICS FOR MARKETING RESEARCH AND DATA ANALYTICS APRIL 2019
- Children's Online Privacy Protection Act (COPPA) 1998
- Health Insurance Portability and Accountability Act (HIPAA) 1996
- Pharmaceutical Research and Manufacturers of America (PhRMA), Code on Interactions with Healthcare Professionals Jan 2009

Appendices

THE PRO FORMAS PROVIDED IN THE FOLLOWING PAGES PROVIDE TEMPLATES BUT MAY NEED TO BE ADJUSTED TO TAKE INTO ACCOUNT LOCAL/NATIONAL REQUIREMENTS.

Pro Forma 1 – Recruitment Agreement

Receipt of Incentive	
Project Details	
Project Title:	Project No:
Agency:	Agency Contact:
Fieldwork	
Date of receipt:	Start Time:
Location: (If online or telephone, please state this)	Duration:
Incentive	
Incentive Type: (e.g. cash)	Incentive Amount:
Declaration	
I confirm that the information I have given during the course of this interview/group discussion represents my views on the subject matter. I confirm that I have received the incentive detailed above in appreciation for my contribution to the project.	
Market Research Subject Signature	
Signature:	Name (please print)
Market Research Subject Code Number	
Code Number	

Pro Forma 2

Receipt of Incentive	
Project Details	
Project Title:	Project No:
Agency:	Agency Contact:
Fieldwork	
Date of receipt:	Start Time:
Location: (If online or telephone, please state this)	Duration:
Incentive	
Incentive Type: (e.g. cash)	Incentive Amount:
Declaration	
I confirm that the information I have given during the course of this interview/group discussion represents my views on the subject matter. I confirm that I have received the incentive detailed above in appreciation for my contribution to the project.	
Market Research Subject Signature	
Signature:	Name (please print)
Market Research Subject Code Number	
Code Number	

Pro Forma 3

Market Research Subject Consent Allowing Client Access to Market Research Fieldwork	
Project Details	
Project Title:	Project No:
Agency:	Location of Fieldwork:
Date of Fieldwork:	Start Time of Fieldwork:
Declaration	
I understand that the company that commissioned this Market Research study	
(name of recipient organisation(s) may or may not be required will: DELETE AS APPROPRIATE - Watch through a one way mirror (watching organisations do not need to be named) but type of organisation(s) should be specified - Listen to an audio recording at their offices (organisations listening in may or may not need to be named depending on whether audio information is considered personal data or not) - Watch a video recording at their offices (watching organisation(s) must be named but naming may be delayed until the end of the interview if viewing is not live) I understand that the purpose(s) of the company having access is:	
The people in the company who will listen to or view the recordings will be in the following functions/roles:	
I understand that all those listening, watching or viewing the recording MUST respect the confidentiality of all information exchanged in Market Research interviews/groups and that no sales approaches will ever be made to me as a consequence of the company having this access. I understand that I can withdraw my consent at any stage. IF APPROPRIATE We would prefer not to reveal the name of the healthcare/pharmaceutical company until the end of the interview, just in case knowing this affects any responses. Is this acceptable to you or not? YES NO	
Signatures	
I have read, understand and agree to the terms above.	
Market Research Subject Signature:	Name (please print)
Agency Signature:	Name (please print)
Market Research Subject Code Number	
Code Number	

Pro Forma 4

Client Agreement to Safeguard Confidentiality of Recordings of Market Research Fieldwork	
Project Details	
Project Title:	Project No:
Agency:	Location(s) of Fieldwork:
Date(s) of Fieldwork:	Start Time(s) of Fieldwork:
Commissioning Client Company	
Declaration	
On behalf of **<the commissioning client company>** I can confirm that the recording(s) of Market Research fieldwork from the above study will only be used for the following purpose(s):	

The only people in the company who will listen to or view the recordings will be in the following functions/roles:	
And the recording(s) will be in the secure care of:	_____
On behalf of the commissioning client I can confirm that:	
- Those listening to or viewing the recording will respect the confidentiality of all information exchanged in Market Research interviews/groups - No sales approaches will ever be made to MR subjects as a consequence of having this access - No attempt will be made to reverse any anonymisation - The recordings will be stored securely, kept separate and processed in accordance with applicable data protection/privacy laws and Market Research professional codes - The recordings will be destroyed or handed back to the agency as soon as is required. - If video streaming has been used to allow remote viewing it is possible that the video transmission system used delivered a copy of the recording to the receiving computer. If this is the case any copy of the video stream saved on the observer's computer MUST be deleted.	

Signatures	
I have read, understand and agree to the terms above	
Company Signature:	Name (please print)
Agency Signature:	Name (please print)

Pro Forma 5

Observer Agreement	
Project Details	
Project Title:	Project No:
Agency:	Agency Contact:
Location of Fieldwork:	Date of Fieldwork:
	Time of Fieldwork
Declaration	
I understand that I MUST be familiar with and adhere to the EphMRA's Observers' Guidelines.	
Observer Signature	
I have read, understand and agree to the terms	
Signature:	Name (please print)

Observers' Guidelines

Client observers MUST be introduced openly and honestly to Market Research subjects. Actual company identity does not necessarily have to be revealed and if it does, it may be withheld until after fieldwork if this information is likely to bias the discussion.

Clients or their sub–contractors MUST NOT be passed off as members of the research agency.

Observers MUST agree to withdraw from observing if any Market Research subject is known to them or recognised to protect the Market Research subject's anonymity. If an observer knows that they will subsequently have to deal with a Market Research subject, the attendee MUST also withdraw from observing. However, if Market Research subjects are made fully aware of the presence of an observer known to them and give explicit consent for that individual to observe then that person may remain at the session, care should be taken that the Market Research subjects are completely comfortable if 'put on the spot' in this way.

Observers MUST respect the confidentiality of all information exchanged in Market Research interviews/groups. They MUST NOT:

- Record any Market Research subject's personal data or record any information with the specific aim of establishing the identity of a Market Research subject;
- Not make any separate identifiable notes or recordings that could be attributed to an individual Market Research subject;
- Attempt to influence how any Market Research subject is approached in future for sales/promotion;
- Not use information gleaned from the observation to amend or build databases.

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