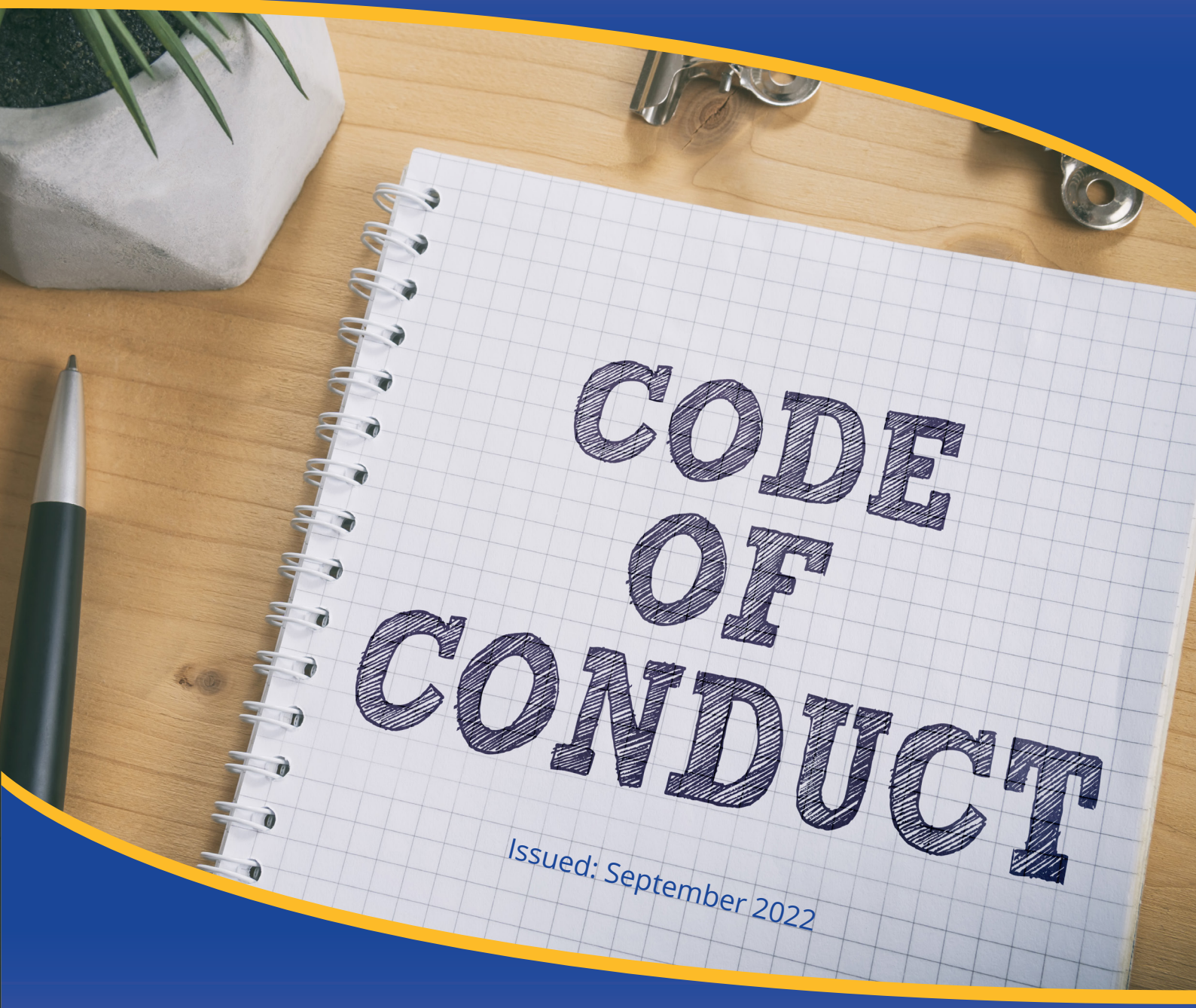
ephmra
excellence - community - standards



Issued: September 2022

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

2022 CODE OF CONDUCT

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 internationally, 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 plus the European Union (EU).

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 including the EU General Data Protection Regulation (GDPR).

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 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.

EPHMRA's Code covers healthcare Market Research and must be distinguished from Promotion of Medicinal Products activities covered by other pharmaceutical industries codes e.g. IFPMA, The International Federation of Pharmaceutical Manufacturers & Associations or EFPIA European Federation of Pharmaceutical Industries and Associations.

Country Codes & Privacy Legislation References

Australia

The Research Society (TRS)
Code of Professional Behaviour
https://researchsociety.com.au/standards/code-of-professional-behaviour

Medicines Australia (MA)
Code of Conduct
https://www.medicinesaustralia.com.au/code/about-the-code/code-of-conduct-current-edition/Australian

Privacy Principles Guidelines
https://www.oaic.gov.au/privacy/australian-privacy-principles-guidelines/

Brazil

Associação Brasileira de Empresas de Pesquisa (ABEP)
Código de Auto-Regulamentação da Atividade de Pesquisa de Mercado, de Opinião Pública e de Mídia
http://www.abep.org/codigos-e-guias-da-abep

INTERFARMA

Código de Conduta
https://www.interfarma.org.br/condigo-de-conduta/

Lei Geral de Proteção de Dados Pessoais (LGPD)
http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2018/Lei/L13709compilado.htm

Canada

Canadian Research Insights Council (CRIC)
Code of Market, Opinion, and Social Research and Data Analytics

https://canadianresearchinsightscouncil.ca/standards/

Innovative Medicines Canada (IMC)
Code of Ethical Practices
http://innovativemedicines.ca/ethics/code-of-ethics/

Canada Privacy Laws
https://www.priv.gc.ca/en

Denmark

Lif The Danish Association of the Pharmaceutical Industry (LIF)
Guide on Market Research
https://www.enli.dk/en/rules/

Finland

Finnish Association of Marketing Research Agencies (FAMRA)
Code of Ethics
https://www.markkinatutkimusliitto.fi/eettiset_saannot

Pharma Industry Finland (PIF)
Code of Ethics
https://www.pif.fi/responsibility/marketing/ground-rules-for-marketing.html

France

Association des Sociétés d'étude de l'Opinion et du Comportement dans le domaine de la Santé
Bonnes pratiques and règles (ASOCS)
http://www.asocs.info/pratique/generalites/

Les Entreprises du Médicament (LEEM)
Transparence et déontologie
https://www.leem.org/transparence-et-deontologie

Germany

Arbeitskreis Deutscher Markt- und Sozialforschungsinstitute e.V.(ADM)
https://www.adm-ev.de/en/standards-guidelines/#anker6

Greece

The Market Research and Public Opinion Companies Association (SEDEA)
https://sedea.gr

Hellenic Association of Pharmaceutical Companies (SFEE)
Code of Ethics
https://www.sfee.gr/sfees-code-of-ethics/?lang=en

Italy

ASSIRIM
Il Codice delle Ricerche
https://www.assirm.it/qualita-delle-ricerche/codice-di-etica-professionale/

FARMINDUSTRIA
Codice deontologico
https://www.farmindustria.it/english-content/

Japan

Japan Marketing Research Association (JMRA)
https://www.jmra-net.or.jp/Portals/0/aboutus/en/index.html

Japan Medical Marketing Research Group (JMMRG)
Handling Personal Information When Conducting Market Research
https://www.medi-ken.org/en/index.html

Act on the Protection of Personal Information and Amendment Act
https://www.ppc.go.jp/en/legal/

On 24 March 2021, the Japanese government released the effective dates of substantial amendments to the Japanese Act on the Protection of Personal Information ("APPI"). The revised Act (Act No. 57 of 2003 as amended in 2015) will fully come into effect on 1 April 2022; however, parts of the amendments are effective earlier. Effective 1 October 2021, use of the "opt-out" exception for data subjects' consent will be restricted; in effect since 12 December 2020 are the amended provisions that raised penalties to fines of up to 100,000,000 JPY (about USD 1 million) in case of violation of an order from the authority or illegitimate use of data.

Mexico

Asociación Mexicana de Agencias de Inteligencia de Mercado y Opinión AC (AMAI)
Estándar de Servicio para la Investigación de Mercados en México
https://www.amai.org/descargas/ESIMM_3_0.pdf

Consejo de Ética y Transparencia de la Industria Farmacéutica (CETIFARMA)
https://www.cetifarma.org.mx/codigos/

Netherlands

Expertise Center voor Marketing-insights, onderzoek en analytics MOA
https://www.moa.nl/
https://www.moa.nl/profgroep-healthcare.html

Dutch innovative pharmaceutical sector Code
https://publicaties.verenigninginnovatievegeneesmiddelen.nl/magazine/code-uk/code_values_and_standards/

Norway

The Strategy and Analysis Association - formerly the Norwegian Market Analysis Association (NMF)
http://www.analysen.no/om-oss

The Association of the Pharmaceutical Industry 2021 (LMI)
The Rules
http://reklameregler.lmi.no/wp-content/uploads/2017/01/LMI-Industry-Rules-2021.pdf

Poland

Organizacji Firm Badania Opinii i Rynku (OFBOR)
Kodeks Dobrych Praktyk
https://www.ofbor.pl/index.php/standardy#kodeks

The Employers' Union of Innovative Pharmaceutical Companies (INFARMA)
Code of Good Practices valid from 1 January 2021 (first edition)
https://en.infarma.pl/ethics/code-of-good-practices/

Russia

Association of International Pharmaceutical Manufacturers Code of Practices (AIPM) http://www.aipm.org/en/ethics/aipm-code/

Data Protection Legislation is composed of the following
Federal Law of 27 July 2006 No. 152-FZ; an unofficial English version as of 2019 is available here
The Amendments came into force on 1 March 2021 and significantly change the legal landscape with regard to the use of publicly available personal data, while also clarifying the conditions of consent to the further processing of such data.
Federal Law of 27 July 2006 No. 149-FZ;
Code of 30 December 2001 No. 195-FZ; and
Criminal Code of 13 June 1996 No. 63-FZ.
Federal Law of 30 December 2020 No. 519-FZ
Federal Law of 24 February 2021 No. 19-FZ on Amendments to the Russian Code of Administrative Offences), increasing administrative penalties for the breach of personal data laws.

South Korea

Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA)
Code of Practices
https://www.kpbma.or.kr/attach/englishResource/Code_of_Practices(KPMA).pdf

Personal Information Protection Act (PIPA)
https://www.privacy.go.kr/eng/laws_view.do?nttId=8186&imgNo=3

Spain

Insights + Analytics España (I+A)
Códigos autorregulación
https://ia-espana.org/codigos-de-autorregulacion/

CODIM Código de Conducta para el tratamiento de datos de carácter personal por organizaciones de Investigación de Mercados
http://www.codim.es/codim/index.php

FARMAINDUSTRIA
Código de Buenas Prácticas de la Industria Farmacéutica 2021
https://www.codigofarmaindustria.org/servlet/sarfi/elcodigo.html

Sweden

Ethical Rules for the Pharmaceutical Industry in Sweden (LIF)
https://www.lif.se/globalassets/etik/dokument/ler-english-version-2020-0501-jd-24apr-pdf.pdf

Turkey

The Turkish Market Research Association (TUAD)
https://tuad.org.tr/en

Association of Research-Based Pharmaceutical Companies (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 (MRS)
MRS Code of Conduct
https://www.mrs.org.uk/pdf/MRS-Code-of-Conduct-2019.pdf

British Healthcare Business Intelligence Association (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

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. Members are required to double check state by state guidance.

The Insights Association (IA)
Code of Standards and Ethics for Marketing Research and Data Analytics
https://www.insightsassociation.org/Tools-Resources/Codes-of-Standards

The Physician Payments Sunshine Act
The Physician Payments Sunshine Act: The Insights Industry Position (insightsassociation.org)

FAQs: Compliance with the Physician Payments Sunshine Act (insightsassociation.org)

Maine:
Maine Finalizes Pharmaceutical Regulations, Clarifying the Legality of Research Respondent Incentives for Physicians (insightsassociation.org)

Minnesota:
Minnesota Restrictions on Pharmaceutical Marketing Research with Medical Practitioners (insightsassociation.org)

EUROPE

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

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.

Children - Means individuals for whom permission to participate in research must be obtained from a parent or responsible adult. Definitions of the age of a child vary substantially and are set by national laws and self-regulatory codes.

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 / Participant / Respondent - 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 - The 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 - 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) - An online community created specifically for the purposes of market, social and opinion research. Others include DORC (Dedicated Online Research Community).

Participant / Data subject / Respondent - Any individual whose personal data is used for Market Research.

Passive social media monitoring - 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.

Personal data - 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.

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 personal data has been irreversibly anonymised is no longer 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. Pseudonymisation is only a security measure, the data is still classified (under GDPR) as personal data. In addition. Researchers must make sure that pseudonymised data cannot be traced, or an individual's identity inferred by deduction

NOTE on definition of Personal Data:

- ***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.*
- ***Comment: The California Privacy Rights Act (CPRA)****, a ballot measure approved by California voters in November 2020, and known as Proposition 24 was approved by California voters on Nov. 3, 2020. It significantly amends and expands the CCPA, but most of the provisions revising the CCPA won't become "operative" until Jan. 1, 2023. The CPRA will take effect in Connecticut, Utah, Virginia and Colorado. Enforcement of the CPRA will not begin until July 1, 2023, and enforcement will apply only to violations occurring on or after that date. It should be noted, however, that the CCPA's provisions remain in effect and enforceable until that date.*

Primary Market Research - Is original data generated and 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.

Processing of personal data - Is Any operation or set of operations performed on personal data, including, but 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.

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 - Environment in 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 - 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 - 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 or organisation who identifies and invites Market Research subjects to take part in a Market Research project.

Research - Includes all forms of market, opinion and social research and data analytics, is the systematic gathering and interpretation of information about individuals and organisations. It uses the statistical and analytical methods and techniques of the applied social, behavioural and data sciences to generate insights and support decision-making by providers of goods and services, governments, non-profit organisations and the general public.

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

Respondent / Participant / Data subject - Any individual whose personal data is used for Market Research.

Secondary Market Research - Collecting and using data that already exists. This data is re-used and reanalysed; it is data already gathered for one use that is then utilised for another purpose.

Sensitive or special category personal data - 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 they are a member of a trade union; their physical or mental health or condition; their sexual life; the commission or alleged commission by them 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.

Scraping - A process of extracting data from social media data for analysis. This can be automated or done manually.

Social media data - 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 - Market Research 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

Distinguishing Market Research from other purposes

1.1 Market Research, which includes all forms of opinion and social research and data analytics, is the systematic gathering and interpretation of information about individuals and organisations. It uses the statistical and analytical methods and techniques of the applied social, behavioural and data sciences to generate insights and support decision-making by providers of goods and services, governments, non-profit organisations and the general public.

1.2 It is defined by the following key characteristics[1]:

- 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;
- Cooperation is voluntary and is based on adequate, and not misleading, information about the general purpose and nature of the project;
- 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.

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 above.

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 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.

Country Specifications

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 mean to promote to and/or reward participants. Market research should not be implemented as competitions or quizzes or in any other manner that could lead to confusion as to the purpose of the Market Research.[2] Participants' co-operation in a project is entirely voluntary at all stages. Members must not mislead participants when asking for their co-operation.[3] Professional activities must be legal, and conform to all relevant legislation, including in particular the Privacy Act 1988 and the Australian Privacy Principles (APPs). *Comment: The requirements to ensure compliance under the APPs include practices, procedures and systems and the need to have a privacy policy which is readily available to participants from whom information is being collected.*

In Brazil: All companies must comply with national and international laws ABEP – Brazilian Association of Research Companies and ICC / ESOMAR rules governing the activity of research, consonant to good market practices. Market research must never be a) Biased; b) Used as a means of promoting sales; c) Used for off-label promotion purposes; d) Used to influence the opinions of interviewees; e) Carried out in a way that can reduce trust in the company.[4]

In Canada: Market research links the consumer, customer and public to the marketer through the gathering of anonymised respondent information – for the sole purpose of pointing out and defining marketing opportunities and issues; generating, refining, and evaluating marketing programs; monitoring marketing performance; identifying patient and prescriber needs and improving understanding of the marketing process. Market research details the information needed to address these issues, designs the method(s) by

1 Based upon the definition of Market Research contained in the ICC/ESOMAR International Code on Market, Opinion and Social Research and Data Analytics. 2 MA. 3 TRS. 4 Interfarma.

which anonymised respondent information is to be collected, manages and/or implements the data collection process, analyses the collective results, and communicates the findings and their implications. Market research should always be conducted for the sole purpose of collecting legitimate market information, following proper and accepted principles guiding the collection and dissemination of Market Research information and the treatment of the respondent(s) and the information they provide. The Market Research questionnaire or program should not be designed in a manner that could be interpreted as leading to a specific response or product conclusion. More specifically, the Market Research program should not be designed to sway the opinion(s) of the participant(s) directly or indirectly about Member Prescription Medicines and should not be used to convince or promote the use of Member Prescription Medicines, as a disguise for selling or developing sales contacts, or as a substitute or disguise for clinical research. Members are committed to separating Market Research from other types of activities unrelated to the sole purpose of gathering of legitimate market information.[5]

In Denmark: Pharmaceutical Market Research studies are characterised by being a structured collection of data that, e.g. can be used to investigate the market in relation to specific medicines, medicines groups, areas of disease, etc. Market research typically has a commercial purpose and can be used to support commercial and product specific decisions and strategies. A company can, by means of Market Research, get the reasons why sales of a medicine are more or less successful. Market research may include payment for the service provided by the healthcare professional, who can receive a fee for their participation in the survey. Market research aims to investigate market conditions and will typically be used for the company's internal use. If a Market Research study does not contain information on medicines, either directly or indirectly, and only mentions health and illness at a general level, there will in principle be no advertising. The fact that medicinal product names are mentioned in a Market Research does not automatically mean that the Market Research is regarded as advertising. Whether the Market Research is considered an advertisement will depend on a specific assessment of, among other things, the setup and wording/content of the questions in the study. The person who prepares the questions for a Market Research study must, among other things, be aware of whether the questions are leading, including whether you in the study, e.g. place the company's own medicine in a particularly favourable light. However, it is noted that it is the form and content of the Market Research that form the basis for the overall assessment of whether advertisement is involved. If the purpose is to promote the prescription, delivery, sale or consumption of medicines, this will be an advertising activity. If, on the other hand, the purpose is merely to acquire knowledge for, e.g. to support commercial and product-specific decisions and strategies, there will not be the same presumption that this is an advertising activity. A market research study may have several purposes.

In Finland: Market research also comprises opinion polls. Market research can be used to obtain information, e.g. about medicinal behaviour, use of medicines and treatment practices, with the objective of promoting patient safety and the correct use of medicines. Market research cannot include any marketing elements.

In Germany: Studies in market, opinion and social research are considered to constitute scientific research within the meaning of Article 5 Paragraph 3 of the German Constitution (Grundgesetz für die Bundesrepublik Deutschland) as well as Article 13 of the Charter of Fundamental Rights of the European Union and Article 179 of the Treaty on the Functioning of the European Union. In principle, they aim to obtain generalisable findings and they must be carried out in accordance with the object of research and the interest in those findings, using appropriate methods and techniques of empirical research (requirement to adhere to scientific methods).

- Studies in public health service for purposes of market and social research are subject to the same ethical and professional rules of conduct and methodological quality standards as all studies in market and social research. The principles and rules of professional conduct in market and social research require, among other things, that the voluntary nature of participation be clearly pointed out, the anonymity of the participants be strictly safeguarded, and the market and social research be clearly differentiated from other activities.
- That means in concrete that no personal data of the participants will be transferred to the client of the study or any other third parties [in a form that allows identification]. The research findings will be transferred only in a form which does not allow for conclusions being drawn about single participants. Moreover, these rules mean in concrete that neither before, during or after conducting a study the selected participants will be specifically and individually contacted for non-research

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purposes of information, advertising or sales promotion nor certain attitudes in terms of the way they carry out their profession will be expected.

In Greece: Market research refers to any systematic data collection and analysis of opinions or positions of persons or organisations with the application of the methods of the applied social sciences aiming to support people or bodies in making a decision. Market research is a valid method for recording the data and characteristics of the pharmaceutical market. Market research is different from the non-interventional studies), have a commercial purpose and are intended for internal use. Market research must be unbiased, must not be focused on promoting sales, and must not aim at influencing the opinion of the participants and is conducted for exclusively commercial purposes. Market Research shall be a snapshot, even if it refers to past or future intentions, always to random/representative sample of population.

In Japan: The Japan Medical Marketing Research Group published Guidelines on *Handling Personal Information When Conducting Market Research* (available here https://www.medi-ken.org/en/index.html) meant to support both pharmaceutical companies and Market Research agencies to maintain and develop pharmaceutical Market Research without creating any misunderstandings. It is specified that:

- Market research is not sales promotion, it is essential that the research content not be slanderous, offensive, or excessive;
- Qualitative/quantitative research results that could lead to the identification of individuals will not be provided in the deliverable data will not be delivered;
- **Considerations of Identifiable Personal Information**
  - 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
- **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).

- **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;
  - Requests for audio/visual deliverables are very common in research intermediated by advertisement agencies/consulting firms. It is common to hear, 'I got them last time' or 'Other agencies will do it for me'. Therefore, please do not forget to have the pharmaceutical/medical device companies be very careful when conducting research intermediated by advertisement agencies/consulting firms;
  - When creating hypothetical Q&As to be used in interviews, please make sure the original content is altered, and is not used as is.

In Norway: Market surveys are a means of acquiring knowledge of the marketplace and of preparing promotional and informational activities. Market surveys should not be carried out for purpose of influencing respondents, communicating promotional messages or encouraging promotional relationships.

In Russia: AIPM defines Marketing study - a study designed to obtain information about the market and to explore the behaviour and perceptions of consumers and interested parties in said market; Marketing studies should not be used for the purposes of: promoting or selling of any pharmaceutical products or managing the opinions or conduct of the participants of the study. For that reason, it is necessary to avoid references to the trade name of the relevant pharmaceutical product unless the purpose of the study requires otherwise; gathering the personal data of patients; conducting the follow-up studies of the efficacy or safety of any pharmaceutical product; pre-registration promotion for any pharmaceutical product or the indications for its use that are subject to registration; obtaining confidential information about competitors; discrediting the pharmaceutical products of any competitor or otherwise causing detriment to any competitors.

In South Korea: KPBMA members may conduct Market Research for the purpose of collecting market-related materials

In Spain:[6] Market research (including social and opinion research) consists of the systematic compilation and interpretation of information on individuals and organisations using statistical and analytical methods and social science techniques that are applied in order to obtain new perceptions or to provide elements that support decision-making.

In these studies, the identities of the interviewees are not revealed to the user of the information without their expressed consent, nor are interviewees contacted for sales activities that result from the information they provide.

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Notwithstanding applicable legislation, there is a general ethical framework within which Market Research must be conducted, as shown in the ICC/ESOMAR International Code for the Practice of Social and Market

Research from the European Society of Marketing and Opinion Research (ESOMAR). In the specific case of the pharmaceutical industry, the Self-Regulation framework on this material consists of the European Pharmaceutical Market Research Association (EPHMRA) Code of Conduct.

This regulation does not presume to replace the EPHMRA Code, but instead establishes certain mechanisms that guarantee the appropriate execution of these studies in the application of this Code. The EPHMRA Code will be of subsidiary application for the appropriate interpretation of this Code.

All Market Research studies are subject to this article if they are conducted at a pharmaceutical company's initiative, the initiative of several pharmaceutical companies that share business strategies for a product or when a pharmaceutical company hands the study to a third party (research institute, scientific society, etc.) that has undertaken the work at its own initiative.

Market research studies must meet the following requirements:

a) Blinding of the identity of the persons participating in the study. The pharmaceutical company will not have the ability to learn before, during or after the study, the identity of the individuals participating in the study.

b) Anonymous nature of the information collected. The pharmaceutical company will not have the ability to associate the data or opinions obtained with the names of the participants.

c) Aggregate handling of the responses or data obtained.

d) Proportionality between the universe and the sample. Quantitative Market Research studies pursue a level that is representative of the universe. When calculating sample size, if parameters other than those generally used in Market Research studies (simple random sample, 5% margin of error, 95% confidence level and 50% level of heterogeneity), the prior approval of the Code of Practice Surveillance Unit will be necessary.

e) The individual who participates in the study does not know, a priori, and does not have the opportunity to link the study with the pharmaceutical company or with a specific product. Therefore, the pharmaceutical company's sales network cannot play any role in developing and conducting the study. If for legal reasons (General Data Protection Regulation) the person participating in the study must be informed of the identity of the pharmaceutical company sponsoring the study (as the data controller), and provided that the participant agrees to be informed of said identity, pharmaceutical companies shall adopt the necessary measures to ensure that such communication is limited to the extent strictly required, and occurs at the end of their participation in the corresponding study.

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

Any exception to these requirements must receive prior approval of the Code of Practice Surveillance Unit. In particular, the requirements of i, ii and v are included in the Supplementary Rules for Market Research studies associated with a product.

In addition, in order to guarantee that the marketing research studies do not represent an inducement to prescribe, or may contain an incentive that is prohibited under the Code, pharmaceutical companies undertake to:

a) Communicate the study prior to its commencement, in accordance with the provisions of Title II Rules of Procedure for the Control Bodies.

b) Ensure that the study does not modify the physician's prescribing habits or the pharmacist´s dispensing habits.

c) To have a written protocol that clearly establishes the objectives, methodology, anticipated results and use. In this regard, written agreements will be formalised with the professionals and/or entities with whom the studies will be conducted on the one hand and the company sponsoring the study on the other, specifying the nature of the services to be rendered, the conditions for participation and remuneration to the professionals, etc.

d) Remuneration to participating professionals must follow market criteria and be in accordance with the time spent, the work performed and the responsibilities assumed. In addition, it must be appropriately formalised. Remuneration must be monetary. In exceptional cases and with the prior authorisation of the Code of Practice Surveillance Unit, remuneration may be provided in kind.

e) Guarantee that the conduction of the study does not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer medicines.

f) Be approved, prior to execution, by the pharmaceutical company's scientific department or by the Compliance Officer stipulated in article 12.12 of the Code.

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

In Sweden: Market research comprises questionnaires, interviews and focus groups with different goals and structures, and may only have the purpose of obtaining information, opinions and attitudes. Market research may not have the purpose of influencing the respondent, or to supply sales promotional contacts. When companies subject to these cooperation rules have Market Research conducted, the person participating in the research shall comply with the ethical guidelines for Market Research in accordance with ICC/ESOMAR.

Market Research, Ethics Approval and Non-Interventional Research

1.3 Market Research as defined in rule 1.1 does not require Clinical Research Ethics Committee or Independent Review Board approval.[7]

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 defines non-interventional study as:

Non-Interventional Study (NIS): *is a study where the Medicinal Product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the Medicinal Product is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures must be applied to the patients and epidemiological methods must be used for the analysis of collected data.*

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

a. There is a written study plan (observational plan/protocol);

b. In countries where ethics committees are prepared to review such studies, the study plan must be submitted to the ethics committee for review;

c. The study plan must be approved by the Member Company's scientific service and the conduct of the study must be supervised by the Member Company's scientific service;

d. The study results must be analysed by or on behalf of the contracting Member Company and summaries thereof must be made available within a reasonable period of time to the Member Company's scientific service, which service must maintain records of such reports for a reasonable period of time. The Member Company must send the summary report to all HCPs that participated in the study and must make the summary report available to industry self-regulatory bodies and/or committees that are in charge of supervising or enforcing Applicable Codes upon their request. If the study shows results that are important for the assessment of benefit-risk, the summary report must be immediately forwarded to the relevant competent authority; and

e. Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the Member Company's scientific service that will

7 Institutional Review Board in the USA.

also ensure that the Medical Sales Representatives are adequately trained. Such involvement must not be linked to the Promotion of any Medicinal Product.

For further details upon the characteristics of non-interventional studies see EFPIA's Code of Practice https://www.efpia.eu/relationships-code/the-efpia-code/

UK NHS Guidance

The UK National Health Service Health Research Authority (NHS HRA)[8] provides a decision support tool to help determine whether a study should be classified as 'research' or not.

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, Available here http://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2017-1.pdf

UK's Governance arrangements for research ethics committees, 2020 edition describes how NHS/HSC Research Ethics Committees function and specifies when review by an NHS/HSC Research Ethics Committee is required.

"2.3.15 Market research may be undertaken by professional Market Researchers, e.g. for public health research or on behalf of pharmaceutical or medical device companies. Where such research is conducted by professional Market Researchers in accordance with the principles set out in the Market Research Society Code of Conduct or 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, e.g. if it requires approval under the Mental Capacity Acts."

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[9]) 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.

8 https://www.hra.nhs.uk/

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

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.

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 in rule 1.1.

1.5 Members must never undertake any activities, under the guise of research, which aim to manipulate, misled or coerce individuals. This applies throughout the research process including proposal, data collection, analysis and reporting.

1.6 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.

1.7 Researchers must not use data gathered in the context of a MR project for database building.

Examples of Non-Market Research Activities

Non-Market Research projects' 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.
Disguised Promotion	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. To avoid exercises being classified as disguised promotions, Researchers must ensure that: • At recruitment and in the introduction to the Market Research explain clearly what is involved; • There is a 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; • Any guides/questionnaires and stimulus designs are 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 materials refer 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 • Only essential personal data is collected and the necessity for this is explained; • Market Research is not run alongside a non-research exercise.

These definitions are based upon the UK's Market Research Society's Regulations for Using Research Techniques for Non-Research Purposes June 2020.[10]

10 https://www.mrs.org.uk/pdf/MRS%20Regulations%20Using%20Research%20Techniques%20for%20Non-Research%20Purposes%202020.pdf

Combining Research and Non-Research Activities

1.8 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.

1.8.1 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.

Contracts and Agreements

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 these cases, 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 Clients must 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.

1.11.1 In Australia: Researchers must inform clients, prior to work commencing, when any part of the work for them is to be subcontracted outside the Member's own organisation (including the use of any outside consultants). On request, clients must be told the identity of any such subcontractors.

1.12 All parties involved must be bound in a chain by a contract and a data processing agreement

1.12.1 In Denmark: A pharmaceutical company gets an analytics/consulting firm to conduct the Market Research, a data processor agreement must be drawn up.[11]

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 and appropriate data processing agreements are in place.

1.13 Sub-contractors must be bound by the same legal and ethical requirements as the main contractor.

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

2. DATA PROTECTION AND PRIVACY

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

2.2 Data Protection Legislations are a work in progress. Researchers MUST check against latest updates and developments in each Country they intend to cover.

2.3 Only personal data that is NECESSARY to the research should be collected and processed.

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Privacy Policies

2.4 Market Research subjects MUST be provided with an easily accessible privacy notice and 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;
- If their data will be shared or transferred to third countries;
- Their data subject's rights
    - o The right to be informed;
    - o The right of access;
    - o The right to rectification;
    - o The right to erasure;
    - o The right to restrict processing;
    - o The right to data portability;
    - o The right to object;
    - o Rights in relation to automated decision making and profiling.

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

2.6 Privacy notices must be made available by the individual/organisation processing personal data (of the controller, joint controller, and processor – i.e., the client, the agency and any sub-contractor) and must be honoured.

2.6.1 **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. 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.

2.6.2 **In Russia**: The Roskomnadzor has published Recommendations on Drafting the Data Processing Policy.

2.6.3 **In the USA**: Per the Insights Association Code of Standards & Ethics: researchers must have a privacy policy that is easily accessible and publicly available (if appropriate), is easily understood and clearly states their data protection and privacy practices.

Consent

2.7 Members MUST ensure that Market Research subjects give their informed consent before information is collected from them. When collecting and processing special categories of personal data explicit consent must be obtained[12].

- Consent must be a clear, unambiguous, affirmative action. It must be confirmed in a clear and specifically worded statement.

12 See art. 9 GDPR.

- Consent should be 'purpose-specific i.e., limited to one specific purpose. Consent must detail all the key 'terms and conditions' including data protection requirements associated with the Market Research.

2.8 Consent must be collected from all Market Research subjects, both HCPs and non-HCPs.

2.8.1 This is compulsory for **GDPR** countries (researchers should investigate territorial scope ex. Art.3), and a Code requirement in **Australia, Brazil, Canada, Mexico, Turkey and USA**.

2.8.2 **In Australia**: When collecting identifiable research information from participants, including passive data, researchers must ensure that:

a) participants are informed of the name and contact details;

b) participants are 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[13]. 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.

2.8.3 **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.

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

2.9 The consent form must include:

a) the name of the organisation(s) or individual responsible for data collection;

b) the general subject of the data collection;

c) the purpose of the data collection;

d) the type of data collected, particularly special category and/or criminal convictions data;

e) the right to withdraw at any time;

f) whether the data collection is to be recorded and/or observed;

g) who is likely to have access to live or recorded information;

h) date, time, location and duration of fieldwork;

i) the likely length in minutes of the data collection;

j) any costs likely to be incurred by a participant;

k) any incentive offered (nature, rate, etc.);

l) the use of automated decision making (if used);

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m) transfer of data to a third country;

n) retention periods or criteria used to determine retention periods;

o) the right to complain;

p) adverse event and product complaint reporting obligations if appropriate.

2.10 Consents must be verifiable. Records MUST be kept to demonstrate:

- Who consented (name of individual, or another identifier);
- When they consented;
- What they were told;
- How they consented;
- Whether they have withdrawn consent and if so when.

2.10.1 **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."

2.10.2 **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.

Naming the Client

2.11 To meet GDPR requirements, the end client or the commissioning client company must be named in three situations:

a) If they are a data controller or joint data controller

or

b) If they are the source of personal data e.g. they supply a list of names to be used for sampling

or

c) If they receive personal data e.g. they receive non-anonymised audio/video files – live or delayed

These three situations all operate independently.

2.12 The source of the personal data and recipients of personal data must also be named at the time that personal data is obtained.

2.13 If the end client is receiving personal data, they must be named before any transfer takes place.

2.14 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;
- the justification for this should be documented.

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

2.14.1 **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 TRS 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.

For Medicine Australia: 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.

2.14.2 **In Denmark** please refer to point 3.3.2.

Secondary Use of data

2.15 If the secondary use of data includes personal data, there must be a lawful basis for the further processing.

- 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;
- Other aspects to take in consideration are:

  a) The context in which the data was originally collected (in particular the relationship between participants and the original data collector);

  b) The consequences of the proposed secondary processing;

  c) The existence of safeguards.

  d) The data was not collected in violation of restrictions imposed by law, through deception, or in ways that were not apparent to or reasonably discernible and anticipated by the data subject

2.15.1 (e) Any requests from individual data subjects that their data not be used for other purposes are honoured. 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.

2.15.2 **In the USA**[14]: When using secondary data, researchers must:

a) Ensure that the use is not incompatible with the purpose for which the data was originally collected;

14 IA.

b) Ensure that the data was not collected in violation of restrictions imposed by laws or regulations, or in ways that were not apparent to or reasonably understood or anticipated by the data subject;

c) Ensure that the use is not incompatible with the purpose for which the data was originally collected.;

d) Ensure that use of the data will not result in any harm to research subjects and there are measures in place to guard against such harm;

Retention Policies

2.16 Personal data MUST be kept NO LONGER than is required for the purpose for which it was collected.

2.16.1 **In Germany**: 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.

2.16.2 **In Greece**: Pharmaceutical companies are not entitled nor have any legal right under the law to keep lists of patient names.

2.16.3 **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.

Security

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

2.17.1 **In Australia**: Researchers must take reasonable steps to protect identifiable research information: a) from misuse, interference and loss; and b) from unauthorised access, modification or disclosure.

2.18 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.

2.18.1 **In Australia**: Researchers must ensure the security of all information relating to a project.

Comment: Researchers should set a data retention policy for all information and allow for variation of it on a project by project basis according to client requirements. In default of any agreement to the contrary, in the case of ad hoc projects primary field records should be retained for one year after completion of the fieldwork and the research data should be retained for possible further analysis for at least two years.

2.19 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.

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

2.21 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.

In the USA: In addition to the EU GDPR, the 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. Virginia Consumer Data Protection Act "VCDPA"; California Consumer Privacy Act "CCPA" (*please see* ***NOTE on definition of Personal Data for further information***) Massachusetts "General Right to Privacy Law") 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.

International Transfers of personal data

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

2.23 Researchers are advised to acquire the consent of the data subjects prior to transfer data internationally unless they rely on and record an exception under specific country legislation.

2.24 The GDPR[15] restricts transfers of personal data outside the EEA. 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"[16];
- 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.

2.24.1 **In Australia**: Particular care must be taken to maintain the protection of individuals' identifiable research information under the APPs when identifiable research information is disclosed to an overseas recipient[17].

2.24.2 **In Brazil**: The transfer of personal data to other jurisdictions is allowed only subject to compliance with the requirements of the LGPD.

2.24.3 **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).

2.24.4 **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).

15 For more information please refer to https://ec.europa.eu/info/law/law-topic/data-protection_en 16 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. 17. TRS and see https://www.oaic.gov.au/privacy/australian-privacy-principles-guidelines/

2.24.5 **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.

2.24.6 **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.

2.24.7 **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.

Data Protection Impact Assessments

2.25 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.

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

3. MARKET RESEARCH TENETS

Confidentiality and anonymity

3.1 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 or separate consent for transfer of personal data for this purpose has been given.

3.2 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.

3.3 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.

3.3.1 **In Canada**: 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[18].

3.3.2 **In Denmark**: 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[19].

3.3.3 **In France**: Respondents must be assured of anonymity. In order to preserve anonymity, the details relating to the identity of the respondent must be physically separated from the documents containing the information about them, after the necessary quality checks in the field have been carried out[20].

3.3.4 **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 anonymity).

- 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;
- No personal data of the participants will be transferred to the client of the study or any other third parties [in a form that allows identification]. The research findings will be transferred only in a form which does not allow for conclusions being drawn about single participants.

3.3.5 **In Greece**: Data from HCPs referring to patients shall be collected and delivered fully anonymised and in aggregate form.

3.3.6 **In Italy**: Personal or confidential information that is provided during an investigation will not be disclosed without the data subject's consent. It will only be expressed in such a form that allows identification.

3.3.7 **In Spain**: Blinding of the identity of the persons participating in the study is required. The pharmaceutical company will not have the ability to learn before, during or after the study, the identity of the individuals participating in the study. Pharmaceutical companies may only access the identity of participants for the purpose of supervising and controlling the quality of the study. For this purpose, access to this data will be temporary while quality control activities are being conducted and no record of data from participants may remain in the possession of the pharmaceutical company.

18 IMC. 19 ENLI Is it a requirement that a market survey be blinded so that participants do not know who is behind the survey? A: No, a Market Research is not required to be anonymised. If the Market Research is not anonymised / blinded between the pharmaceutical company and the interviewed (most often a doctor), the rules on association must be observed for both the pharmaceutical company and the doctor. This means that the doctor must apply to the Danish Medicines Agency for permission to be associated with the pharmaceutical company. (This also applies if the physician does not receive a fee for his services) and the pharmaceutical company must report annually to the Danish Medicines Agency, on doctors, dentists and pharmacists in accordance with the rules in the Order on Association. If, on the other hand, the study is double-blinded by a third party (agency) and the anonymity be- tween the pharmaceutical company and the doctor is maintained, it is not considered as an association with the company, cf. section 4.1 of the Danish Medicines Agency's guide to doctors, dentists and pharmacists regarding association to pharma and MedTech companies. Note that in the case of an advertisement, there can be no double-blind market survey. 20 CNOM.

Waiving Rights

3.4 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.

3.4.1 **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[21].

3.4.2 **In Denmark**: 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.

3.4.3 **In Finland**: The identity of the data subjects must be kept strictly confidential. If the data subject has consented to forward the data in such a way that their identity can be revealed, researchers must first state to whom the information is to be provided and for what purpose and must ensure that the data are not used for any non-research purposes and that the recipient of the data has undertaken to comply with the provisions of the FAMRA Code[22].

3.4.4 **In Germany**: The requirement of anonymity cannot be overturned by the person concerned agreeing to the data being passed on, supplied or used in a personalised form [a form that allows for identification]. In view of the precedence of anonymity, 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 them should be passed on or made available to the client and other third parties (including internal departments) in a personalised form (as well) [a form that allows for identification], 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 [a form that allows for identification], 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 [a form that allows for identification].

- The collected data may only be passed on or made available in a non-anonymous 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.

Separating Personal and Research Data

3.4.5 **In Germany**: For Market and Social research the collected data and the address data must be separated from each other, and the latter deleted as soon as possible. In single studies the deletion must happen as soon as the quality checks on data collection and if necessary,

21 TRS.

22 FAMRA.

the data editing have been completed. In follow-up or repeated studies, the address data must be stored separately from the collected data until the end of the entire project.

4. BEFORE FIELDWORK

4.1 Researchers must refer to Chapter 2 for privacy and data protection obligations, including disclosure of information and acquiring consent prior to project start.

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

Approval and Registration of Proposals Prior to Fieldwork

4.3 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).

4.3.1 This is a TRS code requirement **in Australia**.

Sample Size

4.4 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.

4.4.1 **In Finland**: 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[23].

4.4.2 **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.

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

4.4.4 **In Spain**: It is required proportionality between the universe and the sample. Quantitative Market Research studies pursue a level that is representative of the universe. When calculating sample size, if parameters other than those generally used in Market Research studies (simple random sample, 5% margin of error, 95% confidence level and 50% level of heterogeneity), the prior approval of the Code of Practice Surveillance Unit will be necessary.

4.4.5 **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. If necessary, the respondent is responsible for obtaining the employer's consent. In case of remuneration for participating in Market Research which has a connection with the participant's practice of its profession, consent from the employer should always be obtained.

Over-Researching Market Research subjects

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

4.5.1 **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. Comment: Participant consent is not required as the Member is disclosing the identified information for a research purpose related to the initial reason for data collection.

23 PIF.

Comment: The Member may only disclose this information to the client after the project is completed, as its use is only for the regulation of contact with the individual for a future research purpose.

Drawing a Sample from a List

Information available in the public domain

4.6 Lists may be drawn from sources readily available within the public domain, but personal data still require a lawful basis for collection and processing. It might not be the consent of the data subject if researchers, in their professional judgment, identify another one.

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.

4.6.1 **In Russia**: Researchers intending to use publicly available personal data, may either: rely on the consent obtained by the controller when making the data publicly available, considering the rules of such use defined by that controller; rely on the consent provided by an individual to the Roskomnadzor, via a dedicated web-based platform to be set up under the law, but also considering the rules of data use defined by the Roskomnadzor; or ensure, on their own, that they have appropriate legal grounds for the use of such publicly available personal data.

Information shared by other sources

4.7 If a list containing personal data (e.g. a detailed list of physicians) is passed to the agency by the client – the client must have the consent for sharing these data and for processing the data for Market Research purposes. The agency must still identify a legal basis for their own collecting and processing. It might not be the consent of the data subject if researchers, in their professional judgment, identify another one.

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 must be revealed to potential Market Research subjects[24]. 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.

24 Under GDPR, the source of the list MUST be named.

4.10.1 **In Australia**: Researchers must disclose the source of the research sample to participants no later than the end of the collection of information, except where the Member and the client have reasonable grounds to decide 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).

Correcting Listed Information

4.11 Researchers have a responsibility to make sure that any personal data they 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 researchers 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 – unless instructed differently. 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.

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.

Snowballing

4.17 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.

Re-contacting Market Research subjects

4.18 Under GDPR, it is possible to re-contact Market Research subjects only there is lawful basis in place for this e.g. consent. So, if researchers think they might wish to contact a Market Research subject again (even if only for simple clarification), they 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.

4.19 Consent for re-contacting purposes must include information 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.

4.20 Consent is not necessary for quality control purposes or data validation, if researchers, in their professional judgment, identify another legal basis.

4.20.1 **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: i. 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.

4.20.2 **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.

Incentives

4.21 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 field research team or the research agency.

4.22 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.

4.23 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

4.24 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.

4.24.1 **In Canada**: Members of IMC should take appropriate steps to ensure Health Care Professionals do not leave any Market Research meetings with any kind of promotional material.

4.24.2 **In Germany**: The awarding of incentives must be conditional only to the formally correct participation in the study, not to any further requirements. Incentives are only a stimulus and a "thank you" for participation and must not be a motive for participation. The latter must be excluded by the agency as far as possible.

- In studies in public health service incentives should preferably awarded as a certain sum of money. As a stimulus and "thank you" incentives must be of neutral nature with respect to the study and the target group. Hence their value must be chosen socially adequate and staggered by professional position and time spent of the participants in a way that awarding them neither bias the sample nor influence the behaviour of the participants. The professional scales of fees (e. g. the scale of fees for physicians) shall be taken as a frame of reference.
- Incentives must not be awarded in form of products or services of the client of the study or in form of such connected with them. Incentives must be awarded only by the research agency conducting the study, not by the client commissioning it.

Free Prize Draws

4.25 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.

4.25.1 **In the UK**: MRS Regulations for Administering Incentives and Free Prize Draws[25] provide further details of the rules.

4.25.2 **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.

4.25.3 **In the USA**: 'Rules Governing Sweepstakes' are provided by the Insight Association and available to members here: *https://www.insightsassociation.org/News-Updates/Articles/View/ArticleID/15523* 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*."

25 https://www.mrs.org.uk

Confidentiality of Recipients' Incentive Data

4.26 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

4.26.1 National tax laws may require storing of personal information related to receiving incentives for a determined amount of time. Researchers should:

- Keep data in a form that shows the date of participation, but does not allow merging with the data collected (this is compulsory in Germany);
- Check against specific country's legislation.

Recruiting HCPs

4.27 When recruiting HCPs researchers must refer to Chapter 2 for privacy and data protection obligations.

4.27.1 **In Canada**: The number of experts surveyed should be reasonable in light of the total number of Health Care Professionals part of that specialty[26].

4.27.2 **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[27]. If a doctor, dentist or pharmacist is associated with a pharmaceutical company, e.g. by participating in a market study, they 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[28].

4.27.3 **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. For more detail, please see http://www.ephmra.org/Country-News

4.27.4 **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.

4.27.5 **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.

4.27.6 **In Poland**: It is allowed to recruit HCPs if there is a contract in place; there exists a legitimate need for the services which has been clearly identified and documented; the number of service providers retained and the extent of the service are not greater than reasonably necessary to achieve the identified need. Limited Market Research, such as one-off phone interviews or mail/e-mail/internet questionnaires are excluded from the this, provided that the HCP, HCO Personnel member or PO Representative is not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration for participation in research complies with market terms.

26 IMC.

27 ENLI.

28 ENLI.

4.27.7 **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; and
- The existence of the services contract should not directly or indirectly oblige the healthcare professional to recommend or prescribe any pharmaceutical product.

4.27.8 **In Spain**: There are Market Research studies that have the objective of learning the opinion of Healthcare Professionals on a specific medicine, to study interest in a product based on its strong or weak points, or, for example, to analyse materials that will be used to provide information about the product's characteristics, etc. In these cases, the Healthcare Professional who participates knows, or may know, a priori, the pharmaceutical company that is developing said study and, in addition, when the aim is to test the content, comprehension, design, ease of presentation or interest in the materials used by companies to promote their medicines, personnel from the pharmaceutical company's marketing or sales departments may also be involved.

4.27.9 **In Sweden**: If necessary, the respondent is responsible for obtaining the employer's consent. In case of remuneration for participating in Market Research which has a connection with the participant's practice of its profession, consent from the employer should always be obtained.

EFPIA members and members of EFPIA-affiliated associations MUST[29]

- *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.

Scheduling of Fieldwork Appointments

4.27.10 **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.[30]

4.27.11 **In Germany**: When arranging an appointment for the participation the agency conducting the study or else the persons or organisations acting on its behalf – i.e., in particular interviewer and fieldwork organisations – should make appointments outside the working hours of the participants. Moreover, the participation of privately or publicly employed persons should happen outside their employer's premises where they normally perform their duties. These regulations must be explicitly pointed out to the commissioned persons or organisations by the research agency. However, the concrete wishes of the participants regarding place and time of the participation must also be taken into account.

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29 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 30 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.

In the case of privately or publicly employed participants if necessary - i.e., if a participant proposes to participate during the working hours and/or in the working rooms – the concerning duties resulting from their employment contract must be re-minded. This reminder must be documented appropriately.

HCPs Recruitment of Patients

4.28 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.

4.29 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.

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

4.30.1 **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).

4.30.2 **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).

Disclosure

4.31 **EFPIA Disclosure Code**[31] 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.

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).

4.32 Other industry regulations or relevant legislation may require for disclosure of transfer of value to HCPs – please refer to the "Country of Disclosure" paragraph within this Code.

When disclosure is required

4.33 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 have been made to HCPs (i.e., Market Research related payments incentives and expenses). 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.

4.34 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.

4.35 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 their personal data will be used – why it is requested;

31 https://www.efpia.eu/relationships-code/

- The consequences of giving or not giving consent (how their personal data will be used);
- Their agreement or refusal must be recorded.

4.36 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.

4.37 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.

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

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

When disclosure is not required

4.40 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.

Disclosure reporting format

4.41 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

4.42 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

4.43 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.

4.43.1 **In Australia**: 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.

4.43.2 **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).

4.43.3 **In France**: Two different legislations regulate disclosure: Loi Bertrand and Loi Anti-Cadeaux. Information may be found within the Country News section of EPHMRA's website.

4.43.4 **In Greece**: The Disclosure of Transfers of Value by Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations applies.

4.43.5 **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.

4.43.6 **In Turkey**: 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.

4.43.7 **In the UK**: See the BHBIA Guidelines section on Disclosure requirements.

4.43.8 **In the USA**: Generally 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. IA 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/News-Updates/Articles/View/ArticleID/15541

https://www.insightsassociation.org/Portals/INSIGHTS/Docs%20to%20link/industry_position-physician_payments_sunshine_act.pdf?ver=XN60XEunp_0tghsS7V56uw%3d%3d

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

Public disclosure

4.44 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.

Reporting responsibility

4.45 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

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

5. DURING FIELDWORK

5.1 Before fieldwork starts all information detailed in Chapter 2 MUST be communicated to Market Research subjects.

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

5.2.1.1 **In Canada**: 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[32].

5.2.2 **In Greece**: Medical sales representatives may not be involved in the conduct of Market Research. The commercial departments of pharmaceutical companies may not become involved in Market Research, save in its planning.[33]

Questionnaire 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.[34]

5.3.1 **In Canada**: A Market Research questionnaire or program should not be designed in a manner that could be interpreted as leading to a specific response or product conclusion. More specifically, the Market Research program should not be designed to sway the opinion(s) of the participant(s) directly or indirectly about Member Prescription Medicines and should not be used to convince or promote the use of Member Prescription Medicines, as a disguise for selling or developing sales contacts, or as a substitute or disguise for clinical research.[35]

5.3.2 **In Denmark**: The person who prepares the questions for a Market Research study must, among other things, be aware of whether the questions are leading, including whether you in the study, e.g. place the company's own medicine in a particularly favourable light.[36]

5.3.3 **In Spain**: The pharmaceutical company's sales network cannot play any role in developing and conducting the study.

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.

Comment: 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.

32 IMC. 33 SFEE.

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

35 IMC. 36 ENLI.

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, July 2020. https://www.mrs.org.uk/standards/mrs-best-practice-guide-Collecting-Data-on-Sex-and-Gender
- Guidance Note on Researching Age Bands for Over 65s. https://www.mrs.org.uk/standards/MRS-Best-Practice-Guide-Age-bands-for-researching-over-65s

Stimulus Material

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

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**: Market Research 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 it is required (country requirement or company policy) to use stimulus materials in a Market Research project, it 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 Product 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 Russia**: It is necessary to avoid references to the trade name of the relevant pharmaceutical product unless the purpose of the study requires otherwise[37].

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.

5.18.1 **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.

5.18.2 **In Denmark**: Medicines that have not been approved for the Danish market must not be mentioned or otherwise used in Market Research with healthcare professionals .

5.18.3 **In Finland**: Market research must not focus on a medicinal product which has not obtained the marketing authorisation.

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 Regulations on Medical Devices (e.g. as applicable in EU or UK or Turkey) 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

37 AIPM.

stimulus material, all products should be collected at the end of the interview.

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

Observation and Recording of Fieldwork

Personal data

5.24 Researchers must refer to Chapter 2 for privacy and data protection obligations.

5.25 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.

Information to disclose

5.26 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.

5.26.1 **In Germany**: Observations of behaviour about which the Data Subjects cannot be told in advance for methodological reasons (e.g. studying their reading behaviour while browsing through a magazine) must not take place in a situation where the observed person is completely alone in a room and may thus assume themselves to be unobserved. Instead of asking the person's consent beforehand, they shall be informed afterwards and asked afterwards to consent to the recordings or results of the observation obtained by other means being used for the purpose of the study. Providing general information before the observation is made (e.g. asking the individual to come to a studio and take part in a test there) is not a substitute for requesting the consent to using the observation after the event.

5.27 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.

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.

Consent Required

5.29 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 and their consent must be acquired before doing so.

5.30 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.

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

5.31.1 **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: 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.

5.31.2 **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.

5.31.3 **In Germany**: Since audio/video recordings involve the storage of original sound and/or image data, it is necessary to obtain the consent of the participants in the discussion or the respondents in the interview (referred to in the following as Data Subjects) to the storage of such data – over and beyond their willingness to take part – before the recording can be made. The consent form must explicitly include details of the recipients to whom original sound and/or image data from the audio/video recordings will be transmitted.

- This consent is only valid in connection with the declarations that must be made in this context towards the Data Subjects, in particular the assurance that research findings will only be presented in an anonymised form and that data will not be transmitted to third parties in such a way as to allow individuals to be identified.
- In order to protect the anonymity of the participants in a group discussion during the group discussion itself (and hence also while it is being recorded), the data subjects must not be addressed by their respective last names. The Data Subjects must be told at the beginning of the group discussion that they must not introduce themselves by their respective last names. Likewise, the Data Subjects should not introduce themselves and address each other by their first names, unless this is necessary for methodological reasons.
- All the different observation and recordings options require that the data subject(s) is/are not known to the End Client. Should this be found not to be the case, either the data subject(s) or the End Client must be excluded from the observation. If the End Client is excluded, the End Client must not receive any recordings either.
- If a representative of the End Client (who is not Market Research agency) wishes to **participate in the group discussion** they must be introduced to all Data Subjects in their capacity as an End Client [in the beginning]; they, as well as any observers, must sign the "Declaration of Commitment by End Clients on Observations and Recordings for the Purposes of Market and Social Research" and the "Personal Declaration of Commitment to

Comply with the Data Protection Requirements of the General Data Protection Regulation" and must send them to the agency/studio beforehand. There are no legal reasons against adopting this procedure, however - depending on the topic - methodological reasons may exist.

- If the End Client wishes to **participate in the group discussion but does not reveal themselves as such**: this procedure may only be adopted if the participation of the End Client is necessary in order to achieve the research goal and if compelling methodological reasons exist that preclude his or her capacity as a End Client from being made known during the group discussion. In addition, it is necessary to examine on a case-by-case basis whether the requirements of a legal basis, such as Art. 6(1)(f) GDPR, are met. Furthermore, this End Client representative and any observers must have signed the "Declaration of Commitment by End Clients on Observations and Recordings for the Purposes of Market and Social Research" and the "Personal Declaration of Commitment to Comply with the Data Protection Requirements of the General Data Protection Regulation" and have sent them to the agency/studio beforehand.

Observation via one way mirror

5.32 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.

5.32.1 **In Germany**: Market Research guidelines require that the client's identity must be revealed if requested.

5.32.2 **In Germany**:[39] 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 as live stream.

Observation via live streaming

5.33 When live viewing takes place via video relay/streaming (with and without archiving), organisation(s) viewing must be named 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.

5.33.1 **In Germany**: If a representative of the End Client (who is not Market Research agency) **observe the event either on site, or via an audio or video conference or via a stream**, is permissible if the Data Subjects have been informed accordingly in advance and have given their consent, and if the persons observing the event have signed the "Declaration of Commitment by End Clients on Observations and Recordings for the Purposes of Market and Social Research" and the "Personal Undertaking to Comply with the Data Protection Requirements of the General Data Protection Regulation", and have sent them to the agency/studio beforehand. In addition, any observations must take place in closed rooms to which only those persons have access who have signed the aforementioned written undertakings and have submitted them to the agency/studio beforehand.

Delayed Observation and Viewing of Fieldwork

5.34 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.

5.34.1 **In Germany**: If the End Client (who is not Market Research agency) receives the audio and/or video recordings for research purposes, it is necessary that:

- The End Client has signed the "Declaration of Commitment by End Clients on Observations and Recordings for the Purposes of Market and Social Research" and the "Personal Declaration of Commitment to Comply with the Data Protection Requirements of the

39 https://www.adm-ev.de/wp-content/uploads/2018/11/RL01_E_Group-Discussions_2006_%C3%9CBERGANG.pdf

General Data Protection Regulation" and sent them to the agency/studio before receiving the recording; and

- All Data Subjects have been informed in advance, with reference to these written undertakings, and have given their consent. A sample "Consent to Video/Audio Recordings and Observations" form.

5.35 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).

5.36 Recordings should not be archived for longer than is required to fulfil the purposes of the study.

5.36.1 **In Germany**: Recordings must be deleted no later than 3 months after receipt.

When a Market Research Subject Withdraws

5.37 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.

Client Awareness of Restrictions on use of Recorded Data

5.38 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

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

Observers' Guidelines

5.40 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.

5.41 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.

5.41.1 **In Australia**: Researchers must inform all observers about their legal and ethical responsibilities[40].

Additional requirements for Germany

For projects carried out in-home and on the premises of End Clients:

- The interviewer and the data subject must always give their consent to the participation of the

40 TRS.

agency / End Client commissioning the research and other participating persons at the time the Data Subjects are recruited;

- Special protective measures must be in place to enforce anonymity, in particular the documented consent of the interviewers must specifically name the client commissioning the research and/or the End Client receiving the research findings;
- The data subject must be informed in the same way as the interviewers, in sufficient time before the study; the data subject must have given his or her documented consent;
- The participating persons must sign the "Personal Declaration of Commitment to Comply with the Data Protection Requirements under the GDPR" and send it to the agency conducting the research beforehand;
- The agency/End Client commissioning the research must have signed the "Declaration of Commitment for Research Agencies Commissioning Observations and Recordings for the Purposes of Market and Social Research" and the "Personal Declaration of Commitment to Comply with the Data Protection Requirements of the General Data Protection Regulation" and have transmitted them to the agency conducting the research before the study is conducted;
- All concerns with regard to the protection of minors must be examined and taken into account with special care before the study commences;
- The Data Subjects must be informed before the study is carried out that they can terminate the interview at any time;
- The addresses of the Data Subjects must not be disclosed to the client;
- Audio, video, photo and streaming recordings may only be made by the agency conducting the research or by its data processors;
- In addition, it is only permissible to conduct in-home observations if the following conditions are met:
  - The Data Subjects must be informed before the study is carried out that they can ask the interviewers present as well as other participants to leave their private home immediately at any time;
  - The addresses of the persons interviewed must not be disclosed to the client even if travelling to the location together and conducting the in-home interview together;
  - Before carrying out the study, the agency conducting the research must ensure that all identifying features (in particular name plates on doorbells or letter boxes, family photos, etc.) are removed or covered up;
  - The presence of the client during in-home observations is only permissible if there are compelling methodological reasons.

Researchers' Responsibilities by Research Approach

Face to Face

5.42 It is good practice for the interviewer to provide an identity card to the Market Research subject.

Telephone

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

Naming the Agency/Researcher

5.44 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

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

Special Precautions When Contacting Mobile Phones

5.46 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.

5.47 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

5.48 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). This is available on the ESOMAR website.

Country Specific Guidance

5.48.1 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.

5.48.2 **In Germany and in the UK**[41]: The use of predictive/auto-diallers is restricted.

5.48.3 **In France**: The use of equipment that directly dials phone numbers and continually calls back a given number until the person answers is prohibited[42].

5.48.4 **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

5.48.5 **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.

5.48.6 **In the USA**: Diallers, artificial or pre-recorded voice messages, and SMS text messages 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.

5.48.7 **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').

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

42 CNOIM.

5.48.8 **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 autodial only with the "prior express consent" of the intended recipient to receive such calls.

5.48.9 **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

5.49 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).

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

5.51 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

5.52 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[43].

Online & Mobile Market Research

Definitions

5.53 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.

5.54 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.

5.55 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[44].

5.56 A Market Research subject's email address or other personal identifiers (e.g. screen or username 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.

5.56.1 **In Germany**: Guideline for Online Surveys applies and should be strictly followed. It is available here https://www.adm-ev.de/standards-richtlinien/

Informed Consent

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

5.58 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.

Privacy and Data Protection

5.59 Researchers MUST post a privacy policy statement. The statement should be easy to find, easy to use and understand, including by children when appropriate (Refer to Chapter 2).

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43 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_Codes-and-Guidelines_Passive_Data_Collection-Observation-and-Recording.pdf

44 https://www.esomar.org/uploads/public/knowledge-and-standards/codes-and-guidelines/ESOMAR_26-Questions-To-Help-Research-Buyers-Of-Online-Samples.pdf These cover panel recruitment, project management, monitoring, maintenance and data protection issues

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

5.61 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.

5.62 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

5.63 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

5.64 In addition to the provision of Chapter 2, 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

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

5.66 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

5.67 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

5.68 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

5.69 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

5.70 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 '*Guideline on Duty of Care*[45]'

45 https://esomar.org/uploads/attachments/ckvkpvo7o02c4cn3v5yxes9nl-grbn-guideline-when-processing-secondary-data-for-research.pdf
https://esomar.org/uploads/attachments/cktega1tf037ysptrfe0s7gdq-esomar-grbn-guideline-on-duty-of-care.pdf
https://esomar.org/uploads/attachments/cktim86vi054wsptru81egz40-guideline-on-primary-data-collection-final.pdf

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

5.70.1 **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.

5.70.2 **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.

In the USA: The Federal CAN SPAM Act and Insight Association 's mandatory Code of Standards requires researchers to obtain the research subject's Obtain the research subject's consent for research participation and the collection of personal data or ensure that consent was properly obtained by the owner of the data or sample source.

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'). If known at the time of data collection, inform research subjects of any activities that will involve re-contact. In such situations, the researcher must obtain the research subject's consent to share personal information for re-contacting purposes. Re-contacting research subjects for quality control purposes does not require prior notification. Researchers must allow research subjects to withdraw at any time. Researchers must also obtain consent from the research subject prior to his/her data in a manner that is materially different from what the research subject has agreed.

5.70.3 **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.

Use of Apps

5.71 Researchers 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.

5.72 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;

- 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

5.73 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.

5.74 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 https://www.esomar.org/what-we-do/code-guidelines

5.74.1 **In Germany**: Websites that use analytics tools MUST give users the chance to opt out.

5.74.2 **For the USA**: The Insight Association provides detailed guidelines with regard to the use of active agent technology within its Code of Standards and Ethics.

Online Access Panels

5.75 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 https://www.esomar.org/what-we-do/code-guidelines

Social Media

Definition

5.76 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).

5.76.1 **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

5.77 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

5.78 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

5.79 Without the data subject'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.

5.79.1 **In the USA**: Per the current Insights Association Code *Researchers must obtain consent when collecting and/or using passive data whenever possible, regardless of method employed. In such situations, researchers also must provide clear and simple methods for research subjects to grant and retract their consent. If a device is shared by multiple individuals, every effort should be made to delete data that is not sourced from the individual that gave consent. Where it is not possible or practical to obtain consent, researchers must have legally permissible grounds to collect the data and must remove or obscure any identifying characteristics as soon as operationally possible.*

5.80 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.

5.81 Quotations containing personal data can only be provided to the client if there is a lawful basis for this e.g. the data subject 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.

5.81.1 **In Germany**: Market Research subject identity must remain anonymous and Market Research subjects cannot be asked to waive their right to anonymity

5.82 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.

5.82.1 **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

5.83 Consent from the site/service owners and data subjects/users MUST be given.

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

5.85 Data subjects must 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.

5.86 Data subjects must 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).

5.87 Researchers must publish a privacy policy/notice on their website.

5.88 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

5.89 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.

ADVERSE EVENT REPORTING PROFORMA

SEE ANNEX 1

6. AFTER FIELDWORK

Analysis and quality control

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

6.1.1 In Australia: When presenting findings or data analytics of a research project conducted on an anonymous basis, Members must ensure that an individual's identity cannot be inferred via deductive disclosure (for example, through cross-analysis, small samples or combination with other data such as a client's records or secondary data in the public domain).

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

Reporting Market Research

6.3 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.

6.4 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.

6.5 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.

6.6 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).

Publishing Market Research

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

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

6.9 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.

6.9.1 **In the USA**: Insight Association members are obliged to:

- Always obtain clear approval from clients to release findings publicly ;Ensure that the findings released are an accurate portrayal of the research data, and that careful checks are performed on the accuracy of all data presented;
- Provide the basic information, including technical details, to permit independent assessment of the quality and validity of the data presented and the conclusions drawn, unless prohibited by legitimate proprietary or contractual restrictions ;
- Make best efforts to ensure that they are consulted as to the form and content of publication when the client plans to publish the findings of a research project. Both the client and the researcher have a responsibility to ensure that published results are not misleading;
- Not permit their name or that of their organization to be associated with the publishing of conclusions from a research project unless those conclusions are adequately supported by the data;
- Promptly take appropriate actions to correct information if any public release is found to be incorrect.

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

Insights Association > Tools & Resources > Codes of Standards

6.9.2 **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.

6.10 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. MARKET RESEARCH SUBJECTS

Patients

7.1 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.

7.2 Health data are classified as special categories of personal data under GDPR: researchers must have the specific consent of the data subject prior collection and processing. For more information refer to Chapter 2.

7.2.1 **In Denmark**: There are certain precautions to be taken regarding a healthcare professional's access to patient records. It is clear from section 40 of the Health Act that a patient is entitled, as a starting point, for a healthcare professional not to disclose information about patients' health conditions, private matters and similar confidential information. However, certain exceptions apply, which are stated in sections 41-46 of the Health Act. Thus, it appears, among other things of section 43 of the Health Act, that in certain circumstances information may be disclosed, among other things the patient's health conditions for purposes other than treatment, if the patient has given (written) consent thereto and the consent is entered in the patient record. It is the healthcare professional who holds a confidential information that determines whether the disclosure of the information is justified. For further information on patient safety, please refer to the Health Act and the Danish Patient Safety Board.

7.2.2 **In Spain**: The Royal Decree 957/2020 regulates observational studies with medicines for human use. The aim of the Decree is to ease the administrative procedures applicable to observational studies considering adopted requirements from the EU level primarily the European Medicines Agency-approved guidance on post-authorization efficacy studies and in Spain with the enactment of Royal Decree 1090/2015 on clinical trials with medicinal products, which introduced the legal concept of observational studies. The Royal Decree considers an "observational study with medicines" to be any investigation with the collection of individual data related to people's health, provided that it does not meet any of the conditions required to be considered a clinical trial established in article 2.1.i) of Royal Decree 1090 / 2015, of December 4, and that it is carried out with the purpose of determining the beneficial effects of drugs, identifying or quantifying their adverse reactions or obtaining information on the patterns of drug use in the population. Observational drug studies should be aimed at complementing the information already known about the drug without interfering with routine clinical practice. Therefore, if a project is collecting anonymised data and/or is not about determining the beneficial effects of drugs, identifying or quantifying their adverse reactions or obtaining information on the patterns of drug use in the population these activities would not meet the definition of observational studies and the Royal decree would not apply.

Simulated Consultations

7.3 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.

7.4 There is no restriction upon the use of protected health information if it has been fully anonymised. Full Anonymisation is particularly difficult to achieve and maintain, researchers must pay extra

attention to anonymisation techniques and confirm the result is in line with the Principles of this Code and the EU GDPR previsions.

Vulnerable Market Research subjects

7.5 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.

ESOMAR Guideline on Research and Data Analytics with Children, Young People and other Vulnerable Individuals are available here https://www.esomar.org/what-we-do/code-guidelines

7.5.1 **In Australia**: Researchers must take special care when collecting information from people in vulnerable circumstances in the community.

Comment: Such people include, but are not limited to, people with disability, those experiencing homelessness or other disadvantage, people with serious medical conditions and people from culturally and linguistically diverse backgrounds. Vulnerable circumstances may be permanent or temporary.

What to Consider When Interviewing Vulnerable Patients

7.6 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?

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

7.7.1 **In the UK**: The Mental Capacity Act 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

7.8 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.

ESOMAR Guideline on Research and Data Analytics with Children, Young People and other Vulnerable Individuals are available here https://www.esomar.org/what-we-do/code-guidelines

7.8.1 **In Australia**: The consent of a parent or responsible adult must first be obtained before collecting information from: a) children, defined as under 14 years, and b) young people, defined as 14-17 years, when sensitive information is being collected.

7.8.2 **In Brazil**: Child must be defined as under 14 and young as between 14 and 17 years old. In the case of children under 14, written parental or responsible adult consent is required. Between 14 and 17 years old, it is recommended to obtain parental consent for controversial issues or products. Children under 18 should not be interviewed for alcoholic beverages, cigarettes and any other product prohibited by law for this age group[46].

46 ABEP Norma ABEP para pesquisa de mercado, opini o e m dia

7.8.3 **In Canada**: A child is to be defined as under the age of 14, a young person as aged 14-17.

7.8.4 **In Italy**: Researchers need to use special care when interviewing minors, children under the age of 13 and vulnerable individuals. For particularly sensitive topics, the limit is extended to young people up to 18 years of age. Informed consent from parents or a responsible adult must be obtained before interviewing children.

7.8.5 **In Mexico**: All those under 18 are considered children.

7.8.6 In the UK: The 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.

7.8.7 **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.

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

Consent

7.9 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 whose definition of the age is set by national laws and self-regulatory codes 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.

7.10 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.

7.11 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

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

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

7.13.1 **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.

7.13.2 **In Mexico**: Written consent from the responsible adult must be obtained for all Market Research with Market Research subjects under 18 years of age.

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

7.13.4 **In the USA**: Researchers must take special care when conducting research with children and other vulnerable individuals. When conducting a research project with such individuals, researchers must: Obtain verifiable consent from a parent or legal guardian for children or other vulnerable individuals when required. Take special care when considering whether to involve children and young people (minors) in research. The questions asked must take into account their age and level of maturity. When working with other vulnerable individuals, researchers must follow all applicable laws and regulations and ensure that such individuals are capable of making informed decisions and are not unduly pressured to cooperate in research.

Online Market Research with Children

7.14 EPHMRA recommends that online research is not conducted with children under the age of 14.

7.15 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 below that set by national laws and self-regulatory codes, the child MUST be excluded from giving further personal information until the appropriate consent from the responsible adult has been obtained and verified.

7.15.1 **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[47].

7.16 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

7.17 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.

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

Researchers' Responsibilities

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

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

7.21 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.

7.22 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.

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

Incentives

7.23 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

7.24 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.

7.25 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

7.26 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

7.27 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.

7.28 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.

Payers and Influencers

7.29 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 Sensitive Topics.

7.30 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.

7.31 If the relevant Data Protection legislation is breached, action can be taken by the appropriate Data Protection Authority in the relevant country. For a list of European Data Protection Authorities see - https://edpb.europa.eu/about-edpb/board/members_en

ANNEX 1 PROFORMA

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: Last name:		
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: Last name:		
Relation to the patient?			
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	
IF YES: Doctor's name: Doctor's contact address:			

APPENDICES

THE PROFORMAS 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

Recruitment agreement	
Project Details	
Project Title:	Project No:
Nature of Project	
Subject and purpose of market research study:	
Methodology and Approach:	
Fieldwork	
Location: (if online or telephone, please state this)	Duration:
Date:	Start time:
Incentive	
Type: (e.g. cash)	Amount:
Respondent signature	
Signature:	Name Print:
Respondent 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.