



CODE of CONDUCT

August 2018

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

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1. Introduction

A. Purpose, Scope and Sources

Purpose

- 1.1 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.
- 1.2 It is an industry-sponsored code that aims to define and safeguard the rights of MR subjects, protecting data integrity alongside the rights of MR subjects.

Geographic Scope

- 1.3 The Code provides international guidelines, although its development has focused upon - Brazil, Canada, Denmark, Finland, France, Germany, Greece, Italy, Japan, Korea, Mexico, Netherlands, Norway, Poland, Russia, Turkey, Spain, Sweden, UK and the USA.
It offers international guidelines rather than country specific detail however key inter-country differences are highlighted where they exist.

EphMRA Members' Code Responsibilities

- 1.4 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.
- 1.5 All market research **MUST** comply with international and national law. This June 2018 update incorporates the impact of new data protection requirements introduced via the General Data Protection Regulation (GDPR) on 25 May 2018.
- 1.6 Whilst incorporating the impact of 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 Practise

- 1.7 EphMRA's Code of Conduct complements other professional codes of conduct/practice e.g. ICC/ESOMAR's International Code of Marketing and Social Research. Where appropriate readers are referred to complementary/ additional sources of information. Local codes should be observed.

2. Principles of the Code of Conduct

- 2.1 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. MR 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 MR 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. MR subjects **MUST** be treated fairly and reasonably, with care and courtesy.
 - V. MR subjects **MUST** be protected for the duration of the study – not harmed, exposed, disadvantaged or made to feel uncomfortable in any way. Confidence in market research **MUST NOT** be abused.
 - VI. Data collection **MUST** be adequate, relevant and limited to the purpose (s) for which it is processed. Researchers **MUST** be transparent about the personal data they plan to collect, the reason(s) it is being collected and who it will be shared with.
 - VII. Data **MUST** be processed fairly and lawfully, and only used for the specific and lawful purposes for which it was obtained. Personal data must be accurate and up to date. It must be processed in accordance with the rights of individuals within national and international data protection and privacy legislation.
 - VIII. There **MUST** be no unauthorised or unlawful processing, loss, destruction or damage to personal data. You must take appropriate technical and organisational measures to keep data safe.
 - IX. Data can only be transferred, to a third party or overseas, when adequately protected.
 - X. Personal data **MUST NOT** be kept beyond the time required to fulfil the immediate purposes of the study.
 - XI. Researchers **MUST** behave ethically; they **MUST NOT** undermine or damage the reputation of healthcare market research. They **MUST NOT** disparage or appear to disparage competing companies or products.
 - XII. Researchers **MUST** conduct market research accurately, transparently, objectively and of appropriate quality.

3. Explanation of Key Principles

Please see the Glossary for clear definitions of primary, secondary, ad hoc and syndicated market research.

B. What Constitutes Market Research

Market Research

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

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

- 3.1 Market research, whatever it is called and whatever approach is used, is defined by the following key characteristics:
- the systematic gathering and interpretation of information about individuals, organisations and market places
 - using the information gathering and analytical methods and techniques of the applied social, behavioural and data sciences
 - its purpose is to gain insight or support decision making
 - the identity of MR subjects will not be revealed to the user of the information without explicit consent (and can ever be revealed in Germany), market research has no interest in the individual identity of MR subjects
 - no direct action e.g. a sales approach will be taken in relation to individuals or organisations as a result of the market research (except following up adverse events when permitted), market research is not a commercial communication or a selling opportunity

Based upon the definition of market research contained in the ICC/ESOMAR International Code 2007

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

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

Secondary Data

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

Market Research, Ethics Approval and Non-Interventional Research 3.4 Market research **does not require** Clinical Research Ethics Committee or Independent Review Board approval.

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

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

EFPIA Requirements

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

- The study is conducted for a scientific purpose
- There is a written protocol
- The study protocol MUST be approved by, and the study conduct supervised by, the Company's Scientific Service
- The study results should be analysed and made available within a reasonable period of time to the Company's Scientific Service and the Healthcare Professionals who participated in the study
- If the study shows results that are important for the assessment of benefit-risk profile of the medicinal product, the summary report should be immediately forwarded to the relevant Competent Authority
- Companies publicly disclose the summary details and results of non-interventional studies in a manner consistent with the parallel obligations for clinical trials
- Companies apply the same requirements (to the extent applicable) to all other types of studies including epidemiological studies, registries and other studies that are retrospective in nature

For further details upon the characteristics of non-interventional studies see Article 15, Non-Interventional Studies of Marketed Medicines within EFPIA's *Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals*.

UK NHS Guidance

- 3.5 The UK National Health Service Health Research Authority (NHS HRA) provides a decision support tool to help determine whether a study should be classified as 'research' or not:
1. Are patients randomised to different groups?
 2. Is there a protocol to be followed?
 3. Are the results generalisable* to the population?
- * Generalisable is defined as the extent to which the findings of a clinical study can be reliably extrapolated from the subjects who participated in the study to a broader patient population and a broader range of clinical settings.

<http://www.hra.nhs.uk/research-community/before-you-apply/determine-whether-your-study-is-research/>

In addition, the NHS HRA provide 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.

Indeed in the **UK**, *Governance arrangements for research ethics committees A harmonised edition* published by the Department of Health, May 2011 states that:

“2.3.14 Healthcare market research⁷ may be undertaken by professional market researchers on behalf of pharmaceutical or medical device companies. Where such research is conducted by professional market researchers in accordance with the Legal and Ethical Guidelines issued by the British Healthcare Business Intelligence Association (BHBI), it does not require REC review except where otherwise required by law”

Key Differences

3.6 In addition, EphMRA provides a detailed overview of the differences between market research (MR), non-interventional studies (NIS) and patient support programmes (PSP) – see page 10. Key differentiating characteristics between MR and NIS are:

	MR	NIS
Commercial focus/purpose (market behaviour and opportunities) – internal focus	Y	N
Clinical or medical focus/purpose (safety, efficacy or pharmacokinetics) – external focus	N	Y
Epidemiological methods must be used to design the study and analyse the data	N	Y
Must generate scientifically significant evidence	N	Y
Managed by company’s scientific/medical service (rather than commercial)	N	Y

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. In particular, non-interventional studies (or post-marketing authorisation studies as they may also be called) are confused with market research.

Non-interventional research studies involves 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.”*

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

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. In contrast, 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.

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.

3.7 The following table distinguishes between the characteristics of market research, patient support programmes and non-interventional studies.

Differences Between Market Research, Patient Support Programmes 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 or 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 or 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 analyse the data	N	N	Y
Abbreviations used: MR Market Research PSP Patient Support Programme NIS Non-interventional Study Y Yes N No			

Non-Market Research Activities and Purposes

3.8 It is not market research when data are collected for any other purpose than that described above (see 3.1). In general non-research exercises have the following characteristics:

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

These definitions are based upon the UK's Market Research Society's *Regulations for Using Research Techniques for Non-Research Purposes Nov 2010*

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

Combining Research and Non-Research Activities

3.9 When researchers are fulfilling their role as researchers they **MUST NOT** conduct other non-research activities without the prior informed consent of MR subjects. **In Germany** the MR industry guidelines state that market research may not be combined with non-research activities. Market research should be clearly separated and distinguished from any other activity.

Disguised Promotion

3.10 The collection of data to directly create sales or influence the MR subjects' opinions **MUST NOT** be presented to MR subjects as market research, selling **MUST NOT** be carried out under the guise of market research. Judgement by regulators as to whether a market research survey is disguised promotion is likely to be based on the impact of a series of factors, alone or in combination. Researchers must make sure that:

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

- Market research is not run alongside a non-research exercise

Competitive Intelligence

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

Client and Agency

3.12 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. 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 co-ordinating global agencies and local fieldwork suppliers). In which case for the purposes of the EphMRA Code the following definitions apply:

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

3.13 The following key points should be noted:

- All parties involved should be contractually bound in a chain e.g. if pharma' company X's HQ has commissioned international full service agency Y to carry out a multi-country market research study on their behalf and agency Y has sub-contracted fieldwork to fieldwork agency Z who has in turn sub-contracted recruitment of MR 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
- Sub-contractors should be bound by the same legal and ethical requirements as the main contractor.
- For data protection purposes original holders of personal data can, if contractually bound, pass personal data to other parties without seeking the explicit consent of the individuals as long as the data is being used for a purpose for which the original holder has a lawful basis to process the personal data, such as the consent of the individual.
- Agencies may not transfer MR subjects' personal data to the client without the explicit consent of the MR subjects. **In Germany** MR industry guidelines state that MR subjects must remain anonymous to the client. Consequently personal data must never be made available to the commissioning client company unless it can be guaranteed that client personnel will not (now or in the foreseeable future) be able to identify the individuals. Requesting MR subject consent to override this is prohibited too.

C. Data Protection and Privacy

Definition of Personal Data

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

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

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

In the United States the definition of personal data may depend upon the nature and/or subject matter of the information, the way it is collected, other information that may be collected and combined with it, and the use and disclosure of the information by the collector.

- 3.15 Personal data includes data in a range of formats - alphabetical, numerical, graphical, photographic 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.
- 3.16 Once all identifiers linking data to a MR subject have been removed then it is no longer personal data (it has been irreversibly anonymised) and is not covered by the EU GDPR. Researchers may use a unique identifier (e.g. a serial number) to identify a MR 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 MR subject data. If access to the means to reverse the pseudonymised data is available, the data is still classified (under GDPR) as personal data. In addition, researchers must make sure that de-identified data cannot be traced or an individual's identity inferred by deduction.

Processing Personal Data

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

In the EU under GDPR there are six lawful bases for processing personal data but only two are likely to be used regularly within commercial business intelligence – consent and legitimate interests.

Generally speaking consent is used more frequently within MR and legitimate interests in data analytics. Deciding which legal basis to use depends on the circumstances. No single basis is 'better' or more important than the others – which basis is most appropriate to use will depend on your purpose and relationship with the individual. You **MUST** determine your lawful basis before you begin processing, and you should document it. For further explanatory detail please see EphMRA's GDPR guide to 'Legal Grounds for Data Processing', available on the EphMRA website.

- 3.17 Researchers must limit the collection and/or processing of personal data to the minimum required to meet the needs of the market research.

Naming the End Client

- 3.18 There are three situations when the end client/commissioning client company must be named to meet GDPR requirements. These are as follows, if they:
- Are a data controller (see section 4H 4.19)
- OR
- Are the source of personal data e.g. they supply a list of names to be used for sampling (see sections 4G, 4.10 and 4H 4.19)
- OR
- Receive personal data e.g. they receive non-anonymised audio/video files – live or delayed (see section 5L 11.4)

These three situations all operate independently.

Security

- 3.19 Researchers are responsible for the safe handling, processing, storage and disposal of market research and personal contact data.
- 3.20 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.
- 3.21 In addition to the EU GDPR and US HIPAA (Health Insurance Portability and Accountability Act) requirements that personal data be appropriately protected, **in the USA** certain states have legislation requiring specific security safeguards (e.g., Massachusetts) for any organisation in the state or holding data of a state resident, and various regulators (including the Federal Trade Commission and, recently, the Federal Communications Commission), impose broad overall security safeguards subject to enforcement within their jurisdiction.

Storing Agreements about Access to Personal Data

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

Protection of Personal Data when Transferred

- 3.23 Personal data is protected by the provisions of the GDPR even when taken out of the country where the MR subject lives. Personal data must not be transferred from one country to another without the consent of the individual or 'legally permissible grounds' for the transfer.
- 3.24 If personal data is to be transferred from one country to another, the data protection requirements of both countries MUST be met. The transfer of personal data to non-EEA countries is forbidden unless there is adequate privacy protection and specific data protection arrangements in place.

There are various ways in which to comply with the EU Directive in non-EU countries depending upon the circumstances, these include Model Clauses and Binding Corporate Rules (BCR) and in the USA, the EU – US Privacy Shield framework – For further information on these see:
http://ico.org.uk/~media/documents/library/Data_Protection/Detailed_specialist_guides/model_contract_clause_s_international_transfers_of_personal_data.ashx. EphMRA members can access further detail upon the EU – US Privacy Shield framework within the Ethics Country News section on the EphMRA website.

- 3.25 **In Japan** (in accordance to Articles 16 and 23 of The Act on the Protection of Personal Information), personal data cannot be processed or passed to a third party unless the individual has given prior consent. Consent must be given for specific purposes and processing or transfer must be for these purposes alone.

In Mexico the data protection authority differentiates between transmission and transfer of personal data. Transmission is defined as the passing on of personal data for a restricted range of uses and the transmitting party continues to be responsible for the personal data. Transfers of personal data allow a broad range of processing/uses. In both cases, the individuals consent is required.

In Russia (in accordance with Federal Law of the Russian Federation #266-FZ on personal data, article 12, Trans-border transfer of personal data), the MR subject MUST be made aware if their personal data is to be transferred to a foreign customer and give a written consent to this.

MR subjects' Rights to Their Personal Data

- 3.26 MR subjects MUST be provided with a privacy notice which tells them clearly what their rights are. It must include information such as what personal data is collected, how it is used, how it will be managed, how long it will be stored and the conditions under which it will be shared including transferred outside the EU, as well as how to get more information or make a complaint. The privacy notice must be made available by the individual/organisation collecting the personal data and must be honoured by all parties that process the personal data (whether or not they are the originator of the privacy notice).
- 3.27 MR subjects MUST be made aware of their data protection rights and the right to complain to a supervisory authority, their rights include to:
- ask what data is being held about them
 - ask for the data to be amended or destroyed
 - object to processing
 - ask to move their personal data
 - ask to restrict processing
 - exercise their rights in relation to automated decision making and profiling.
 - where the data processing is based and details of any data transfers to countries without adequate data protection

- 3.28 Data Protection in **Mexico** (regulated by the LFPDPPP - Law for the Protection of Personal Data in the Hands of Individuals) requires to meet these minimum requirements:
- Responsible person or committee for personal data safety and privacy issues
 - Defined and auditable internal procedures for the processing of personal data
 - A data privacy disclaimer (“aviso de privacidad”) which makes clear the type and purposes of data collected and processed.

Individuals’ rights are known as “A-R-C-O”: *Acceso* (access) – *Rectificación* (correction) – *Cancelación* (deletion) – *Oposición* (opposition to future data treatment). MR subjects and those processing personal data must be aware of these, MR subjects through the data privacy disclaimer.

Data Localisation Law in Russia

- 3.29 The key requirement of the Data Localisation law states:

Data operators processing data of Russian citizens, whether collected online or offline, are obliged to record, systematize, accumulate, store, update, change and retrieve such data in databases located within the territory of the Russian Federation.

All processing operations affecting the actual records held (collection, updating /amending and deletion of the personal data record) must be carried out on a master/primary database held in Russia. A copy of that database can be transferred and secondary processing (e.g. backup, data analysis, secondary storage and access) can take place using the copy that has been transferred to another country. The copy can also be anonymised, deleted or destroyed. Companies and agencies will have to store and maintain personal data directly collected from individuals resident in Russia in a primary database held on servers hosted in Russia. Cross border transfers (carried out in compliance with Russian data protection law) are still permitted, but the master database containing personal data must still be stored and maintained in Russia.

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

Privacy Rule in the USA - HIPAA

- 3.30 **In the USA**, that part of HIPAA known as 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.*”

D. Market Research Tenets

Informed Consent

- 3.31 Members MUST ensure that MR subjects give their informed consent before information is collected from them.

“cooperation is voluntary and MUST be based on adequate, and not misleading, information about the general purpose and nature of the project when their agreement to participate is being obtained and all such statements shall be honoured.”

<http://www.esomar.org/knowledge-and-standards/codes-and-guidelines.php>

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

Only personal data that is of necessary to the research process MUST be collected.

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

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

3.33 Specific consent is not required for the use of anonymised and non-attributable responses.

3.34 Informed consent guarantees MR subjects the right to withdraw from the interview at any time. This right MUST be made very clear to children.

Confidentiality & Anonymity

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

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

For further information see the ICO’s ‘Anonymisation: managing data protection risk code of practice’
http://www.ico.org.uk/for_organisations/data_protection/topic_guides/anonymisation

3.37 Researchers MUST ensure that information identifying the MR subject (e.g. recruitment questionnaires, attendance lists) is not passed to the client without the MR subject’s consent. Passing a MR subject’s personal data to the client is forbidden by MR industry regulations **in Germany**.

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

Waiving Right to Confidentiality

3.39 The MR subject's right to confidentiality can be waived by the MR subject if specific consent has been sought and granted providing MR 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.

In Germany MR industry guidelines prohibit transferring data that could identify MR subjects to the client.

Separating Personal and Research Data

3.40 **In Germany** MR industry guidelines state that personal data **MUST** be separated from interview data immediately by the research agency, after this the only link allowed between the two is a common code number. The address data – name, postal address, telephone number, email address – **MUST** be destroyed at the earliest possible time i.e. once quality control checks have been completed. Personal data cannot under any circumstances be passed to a client, there are no exceptions or waivers allowed.

ADM Key Problems in the Data Protection Laws and Professional Laws for Scientific Survey Research Aug 2009
http://www.adm-ev.de/fileadmin/user_upload/PDFS/Kernprobleme_E.pdf

Patient Confidentiality

3.41 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 and **in the USA** meet the de-identified criteria within HIPAA (see 19.3 or www.hhs.gov/ocr/privacy/index.html Aug 2009) or as permitted by the HIPAA Privacy Rule provisions related to research or a “limited data set” or if the patient has given explicit authorisation.

4. Key Research Stages - Before Fieldwork

E. Approval and Registration of Proposals Prior to Fieldwork

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

4.2 **In Spain**, Farmaindustria member companies **MUST** provide prior notification to the Farmaindustria Code of Practice’s Surveillance Unit (CPSU) when carrying out, financing or sponsoring market research studies. This is **NOT** mandatory if:

- The pharmaceutical company funds less than 50% of the study OR
- The company does not have access before, during or after study, to the identity of the participating healthcare professionals and has not intervened in their selection beyond defining participating group described in the study protocol OR
- The study does not provide direct or indirect remuneration to the participating healthcare professionals OR
- The study involves paid participation of less than 20 healthcare professionals. It is not allowed to split a study into smaller units that share approach, objectives and methods.

Communication should be addressed to the Farmaindustria Code of Practice Surveillance Unit (CPSU) and sent at least ten working days before the study is due to start. The pharmaceutical company is responsible for reporting the study.

Prior approval from the CPSU is required if the market research could involve any of the following:

- A disproportionate or unusual sample structure in quantitative market research
- Linking the market research to a specific product

- Using results within any publication or promotional material.

However the CPSU recommends that all market research studies carried out in **Spain** should be reported on a voluntary basis (not just those that it is compulsory to report). For full details please see: http://www.farmaindustria.es/Farma_Public_ING/Codigo/codeofsanitaryprofessionals/index.htm

In Spain market research studies MUST be approved before being carried out by the pharmaceutical company scientific service or by the compliance officer in Spain, this is required by the Spanish Code of Good Practices for the Promotion of Medicines and Interaction with Healthcare Professionals.

- 4.3 **In Korea** KRPIA member companies must reports details of surveys quarterly on the form provided by the KRPIA and market research agencies MUST not disclose the identity of participating HCPs to the client company and selection of HCPs MUST be conducted independently by the agency.

F. Data Protection

When preparing a proposal and considering the use of personal data within a MR project that falls within the scope of the GDPR a Data Protection Impact Assessment (DPIA) may be needed (or relying on one previously carried for similar work). DPIAs are only needed in certain circumstances, to find out more about the when DPIAs are needed and how they should be carried out see the BHIA's guide to Risk and Privacy Impact Assessment available at <https://www.bhbia.org.uk/guidelines/gdprupdates.aspx>

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

G. Use of Sub-Contractors

- 4.4 Clients should be informed if any part of the study is to be sub-contracted outside of the agency. If requested the identity of the sub-contractor should be provided. **In Canada**, this is mandatory for MRIA members. If a sub-contractor is employed at short notice after the study has started the client should be informed as soon as practical.

H. Preparing the Sample

Sample Size

- 4.5 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.

Over-Researching MR subjects

- 4.6 Researchers should manage and monitor the frequency with which potential MR subjects participate in market research and try to avoid over-researching individuals.

Drawing a Sample from a List

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

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

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

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

If however local law/regulations demand that the explicit consent of those on the list is required before their personal details are passed on as **in Italy**, this MUST be complied with. **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 MR 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 MR subjects that have chosen to opt-out of or not be contacted for market research must be excluded.

Revealing the Source of a List

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

- the client will be named at the end of the interview
- they can withdraw their consent at any point

The justification for this should be documented.

Correcting Listed Information

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

Adding Personal Data to a Database

4.12 Personal data can be added to the database only if you have a lawful basis for this e.g. the MR subject is told of this intention at the time of data collection. MR 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**.

The MR 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 MR Subject Details

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

Recruitment

Screening Questions and Questionnaires

4.14 Screening questions MUST only be used pre-screen potential MR subjects for participation in the research, they MUST NOT be used to collect additional data.

Physician Recruitment of Patients

- 4.15 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.
- 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.
- 4.16 If the patients reply directly to the agency, which is preferable, the doctor should not be told which patients are going to/have participated.
- 4.17 **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).

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

Snowballing – MR subject supply of Potential MR subjects' Names

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

Recruitment – Information that MUST be Communicated

- 4.19 You must obtain a record of respondents' agreement/consent to participate in MR. This must detail all the key 'terms and conditions' including data protection requirements associated with the MR. This agreement/consent must be collected from all respondents, both HCPs and non-HCPs.

EFPIA members and members of EFPIA-affiliated associations MUST document an agreement between agency or client company and the healthcare professional MR subject in advance of fieldwork (i.e. at recruitment) for all market research carried out face to face. 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. 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>

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

In **Denmark**, nurses must be treated as non-HCPs.

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

In the **UK** the BHBA states that to conform to Clause 20 of the ABPI's Code of Practice 2016, all study types irrespective of methodology require a written agreement; although different mechanisms to capture the agreement may be needed for different methodologies. For full details see the BHBA Guidelines.

<http://www.bhba.org.uk/guidelines/legalandethicalguidelines.aspx>

<http://www.pmcpa.org.uk/thecode/Pages/default.aspx>

EFPIA and local pharmaceutical industry associations' requirements mean the agreement/consent must include:

- Subject and purpose of the MR
- Methodology and approach
- Location and duration of fieldwork
- Date and time of fieldwork
- Reimbursement offered – both the nature and the rate of remuneration
- Adverse event and product complaint reporting obligations if appropriate
 - Templates for a standard text are available **in Germany** (<http://www.akdae.de/Arzneimittelsicherheit/UAW-Meldung/index.html> and <http://www.akdae.de/Arzneimittelsicherheit/UAW-Meldung/UAW-Berichtsbogen.pdf>) and the **UK** (<http://www.bhba.org.uk/guidelines/abpiadverseeventguidelines.aspx>). Furthermore **in the UK** non-healthcare professionals MUST be informed that if adverse events are discussed during the research, then the details will be collected and forwarded to the commissioning pharmaceutical company.
 - In **Mexico**, the privacy disclaimer (aviso de privacidad) has to be provided (in writing or read) to the MR subject, or a source for it given (i.e. hyperlink). MR subjects must consent to the terms of the privacy disclaimer.

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

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

Either in the consent agreement or in an easily accessible privacy notice, respondents must also be made aware of:

- Legal basis for the data processing and if appropriate the legitimate interests of the data controller or third party
- Details of the data protection officer (if there is one)
- How long their personal data will be stored

- The existence of each of the data subject’s rights and the right to complain to a supervisory authority, their rights include to:
 - Ask what data is being held about them
 - Ask for the data to be amended or destroyed
 - Object to processing
 - Ask to move their personal data
 - Ask to restrict processing
 - Exercise their rights in relation to automated decision making and profiling.
 - Where the data processing is based and details of any data transfers to countries without adequate data protection

Naming the data controller, source and recipients of personal data

GDPR requires that data controller(s) relying on consent are named at the time that personal data is obtained as part of the MR process.

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

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

In addition, the source of the personal data and recipients of personal data must also be named at the time that personal data is obtained as part of the MR process (whether or not they are data controllers).

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:

- Respondents must be made aware at recruitment that:
 - the client will be named at the end of the interview
 - they can withdraw their consent at any point
- If the end client is receiving personal data they must be named before any transfer takes place
- The justification for this should be documented.

The requirements for naming the client when observation and recording are taking place are detailed at 11.4.

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

In **Germany**, the FSA Code recommends to members that employer permission (Dienstherrengenehmigung DHG) is sought and granted for healthcare professionals to participate in market research. There is no over-arching legal requirement for a DHG, however if you have to include healthcare professionals and/or federal civil servants e.g. payers (Bundesbeamte) within the market research sample and are committed to adhering to the FSA Codex, you have to check that a DHG is in place. You may do this by including suitable questions within the recruitment screener and ensuring potential MR subjects only participate if they have their employers' permission. The DKG have also stated that employer permission is required unless participation in market research is a one-off or rare and the incentive does not exceed 100 euros. German market research associations have no such requirements.

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

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.

Data Collected at Recruitment

4.21 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.

Scheduling of Fieldwork Appointments

4.22 In **Germany, 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.

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

Disclosure

4.23 Disclosure Code 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).

For the full EFPIA Disclosure Code go to <https://www.efpia.eu/relationships-codes/healthcare-professionals-hcps/disclosure-of-payments-to-hcps/>

When disclosure is required

- 4.23.1 For market research disclosure is required when **pharmaceutical companies are aware of the identities** of those participating in MR it has commissioned and ToVs i.e. MR-related payments (incentives and expenses) have been made to HCPs. In these cases the payments made to **individual named HCP MR subjects MUST be disclosed**, whether they've paid them directly or indirectly via an agency. This information will be made publicly available.
- 4.23.2 National data protection legislation may require the HCP's consent for their data to be used in this way. If this consent is not given, MR payments MUST still be disclosed but on an aggregate basis. So if HCP MR subjects do not consent to their personal data being used for disclosure they may still participate in the MR.

When disclosure is not required

- 4.23.3 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 MR subject is recognised (and identified) by client company personnel, disclosure may not be required.

- 4.23.4 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 MR and disclosure will be required.

Reporting format and Information to be disclosed

- 4.23.5 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.
- 4.23.6 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 – MR incentive
 - MR-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 MR
 - 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

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

Public disclosure

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

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

Individual country/member associations decide upon the route.

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

Reporting responsibility

4.23.9 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

4.23.10 Disclosures MUST be made in the first six months after the end of the calendar year in which the MR payment was made.

Consent and record keeping required

4.23.11 HCPs whose identity will be known to the commissioning pharmaceutical company MUST be advised that disclosure will take place and asked for their consent to pass on their personal data and payment information for this purpose. This must take place as soon as practical, generally at recruitment. As with any request for consent for the use of personal data, the following must be made clear:

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

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 MR), consent for this may be secured at the end of the interview.

MR agencies MUST keep records of the required disclosure information to pass to the pharmaceutical company.

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

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

4.24 **In Denmark** legislation stipulates that any non-double-blinded (i.e. the identity of the commissioning client company is not known to the HCP MR 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).

4.25 **In France** Loi Bertrand imposes a general disclosure obligation on companies manufacturing or commercialising health products or services. It applies to market research carried out with healthcare professionals that takes place in France, whether commissioned from inside or outside

France and requires that agreements between market research agencies and healthcare professionals are publically reported.

<http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000028339198&dateTexte=&categorieLien=id>

It is the responsibility of the commissioning client company to report that they have an agreement with a named market research agency, its date and the purpose of the agreement (i.e. market research).

It is the responsibility of the market research agency (or if used, their sub-contractors) to report:

1. That an agreement with individual named HCPs exists (including a number of key details such as title, speciality, qualifications, RPPS or equivalent number, professional address)
2. The purpose of the agreement e.g. market research
3. The law states that when a benefit valued over 10 euros (including VAT) is to be given it has to be reported by named individual. Market research incentives are considered 'benefits' (based on the Conseil d'Etat decision *1ère / 6ème SSR, 24/02/2015, 369074*). So incentives exceeding 10 euro (including taxes where applicable) have to be reported by named physician. All market research studies involving healthcare professionals that take place in France have to be declared irrespective of whether a benefit or an incentive (or neither) is offered.
4. It should be noted that:
 - The agreed market research incentive should not be disclosed
 - The sponsoring company (and product) should not be named
 - HCP MR subjects MUST be informed of the processing of their personal data
 - This applies whether or not the client company is aware of MR subject identity.

EphMRA suggests that the agency with whom the healthcare professional has the agreement will be the reporting agency.

Reports should be made to the central public website <https://www.entreprises-transparence.sante.gouv.fr/flow/login.xhtml;jsessionid=ECCC896876F382F19E1EB0AF367B227A.sunshine-entreprise>
Reporting for January to June data should be done by 1 Aug and for July to Dec data by 1 Feb.

In France Loi Anti Cadeaux/Loi DMOS (Diverses Mesures d'Ordre Social) requires that the relevant national association/board e.g. the CNOM (physicians) or the CNOI (nurses) etc., is informed of agreements between companies/agencies and healthcare professionals including market research studies, one month before they begin. A reporting template is available on the ASOCs website. It is possible for organisations to apply for annual approval from CNOM in advance of carrying out market research with physicians, rather than on a project by project basis. The terms and conditions of the annual process and the access arrangements are detailed in the July 2016 article 'New and Simplified CNOM Approval System' which is available within the Country News, France section of EphMRA's website.

<http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000006688680&cidTexte=LEGITEXT000006072665&dateTexte=20100914>

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

- 4.26 **In the USA** generally speaking the federal Sunshine Act does not include mandatory disclosure of survey incentives made by pharmaceutical companies or their agents to doctors. While survey payments were included in initial versions of the law and have been the subject of ongoing debate in Congress, the law generally excludes thank you payments for taking part in surveys provided the company sponsoring the research is unaware of the MR subjects' identity. However some state laws are different. The CASRO, PMRG and the MRA Association 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:

<http://www.insightsassociation.org/article/final-physician-payments-sunshine-act-rules-released>

For further details upon US state Sunshine laws see:

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

Re-contacting MR subjects

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

You don't need to obtain their consent before re-contacting them for MR quality control purposes or data validation, these would be very likely to be in the data's controller's legitimate interests but this must be subject to assessment. If you know you'll definitely need to re-contact respondents for a second stage or follow-up research, you must make this clear and get consent for this, at recruitment.

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

4.29 **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 MR subjects is done by means of a code number.

4.30 Transferring personal data outside the European Economic Area (EEA)

You must not transfer personal data outside the EEA unless there are adequate data protection measures in place. The EU Commission provides a list of countries or territories providing adequate protection for data subjects in connection with the processing of their personal data, see the European Commission's data protection website at:

http://ec.europa.eu/justice_home/fsj/privacy/thridcountries/index_en.htm

If you have to transfer personal data to countries outside the EEA or that are not listed as having adequate protection you may consider other means of guaranteeing the personal data you transfer is adequately protected by:

- Using other legal grounds, such as unambiguous consent from individuals for the transfer of their personal data for processing
- Using Model Contract Clauses (as approved by the European Commission)
- Implementing binding corporate rules (BCR's) for transfers within a corporate group or within a group of undertakings, or within a group of enterprises engaged in a joint economic activity.

When transferring data outside of the EEA you must comply with all data protection principles. Fair and lawful processing requires you to inform individuals about transfers of their personal data to other countries.

J. Incentives

Incentives

- 4.31 An 'incentive' is any benefit given to a MR subject to encourage participation in a market research study and should be:
- Dependent only on the correct 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 MR 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, MR subjects' personal data MUST NOT be accessible to company personnel outside the research team.
- MR 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
- 4.32 Panel members should be made aware of the approximate level of commitment and/or length of time required before the incentive will be paid.

Incentives – Country Exceptions

- 4.33 **In Denmark**, ENLI member companies are required to pay incentives to healthcare professionals in cash (cheques, bankers drafts and bank transfers are acceptable). In addition, nurses must be treated as non-HCPs, so incentives should be similar to patients rather than physicians.
- 4.34 **In Greece**, SfEE member companies should not pay incentives:
- To healthcare professionals for fieldwork that lasts longer than 2 hours, fieldwork may last more than 2 hours but incentives cannot exceed 2 hours of incentives
 - Directly to healthcare professionals, the transaction should involve an intermediary e.g. an agency or recruiter. When the market research is undertaken directly by the pharmaceutical company, incentives for healthcare professionals are prohibited.
- 4.35 **In Korea** KRPIA members MUST report market research survey incentives quarterly. Food, drink and "compensatory gifts" up to a value of KRW 100,000 per HCP may be provided. In addition, if the surveys takes 30 minutes or more to answer "compensatory payment" of up to KRW 100,000 per HCP may be provided.
- 4.36 **In the Netherlands** CGR (Stichting Code Geneesmiddel Reclame) guidelines state that incentives should be based upon the hourly tariffs set by the NZa (Nederlandse Zorg autoriteit, the Dutch Healthcare Authority) and that the distinction between the incentive and expenses is clear.
- 4.37 **In Poland and Russia**, if the sum total of incentives paid to a MR subject exceeds a specific level (250 PLN in Poland and 4000 RUR in Russia) within a year, the tax authorities should be advised.

4.38 **In Spain**, payment of incentives MUST be in cash (cheques and bankers drafts are acceptable). Exceptionally, and with the prior authorisation of the CPSU some payments in kind may be made. For further country specific details of incentives regulations, recommendations and preferences please see EphMRA's Overview of Incentives.

4.39 **In Sweden** LIF guidelines state that the maximum incentive should be 2.5% of the current KPI.

Incentives that are Not Allowed

4.40 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 MR subject to spend money
- That are made up of the sponsoring client's goods, services or vouchers for these
- As a covert means (alongside supposed market research questions) to collect personal data.

Free Prize Draws

4.41 With regard to free prize draws, i.e. a draw where prizes are allocated by chance, with no payment to enter, MR 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. The MRS Regulations for Administering Incentives and Free Prize Draws February 2012 provide further details of the rules **in the UK**. 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.

4.42 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.

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


Confidentiality of Recipients' Incentive Data

4.44 The personal data of MR 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

4.45 **In Germany and in Italy** tax laws make it necessary to store the private address data of MR subjects receiving incentives for the length of time required by tax law. The same is true **in Poland** for incentives above a specific level. . **In the Netherlands** tax laws make it necessary to store the confirmation of receipt of incentives, for the length of time required by law. Personal data MUST be

stored in a way that ensures the date of the interview is identifiable but prevents personal data being linked to response data.



5. Key Research Stages – During Fieldwork

K. Information to be Communicated at the Start of Fieldwork

- 5.1 Before fieldwork starts all of the information detailed in section 4.20 MUST be communicated to respondents.
- 5.2 EphMRA does not recommend the use of sales representatives as market research interviewers.

L. Instrument and Stimulus Design and Use

Questionnaire and Question Design

- 6.1 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
 - MR 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
 - MR 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.
- <https://www.mrs.org.uk/pdf/2014-09-01%20Questionnaire%20Design%20Guidelines.pdf>
- 6.2 Market research materials should not:
- Raise unfounded hopes for a treatment
 - Mislead MR 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

- 7.1 When a topic is considered sensitive, MR subjects MUST be told explicitly the subject and content of the discussion. Sensitive topics include those that are judged to be sensitive to most people or a specific group of people because of the nature of the subject or those that may be sensitive to a particular individual, because of that individual's past history.
- 7.2 When sensitive topics are to be discussed, the MR 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.
- 7.3 In cases where the subject under discussion is gender specific or of a sensitive or potentially embarrassing nature, MR subjects should be interviewed by interviewers of the same sex, or given the choice to be so.
- 7.4 If collecting information on sex, gender or age may prove sensitive, the following guidance may be helpful, the UK MRS's:

- Guidance Note on Collecting Data on Sex and Gender, January 2016
<http://www.mrs.org.uk/pdf/Guidance%20on%20Collecting%20Data%20on%20Sex%20and%20Gender.pdf>
- Guidance Note on Researching Age Bands for Over 65s, July 2016
<https://www.mrs.org.uk/pdf/MRS%20Best%20Practice%20Guide%20Age%20bands%20for%20researching%20over%2065s.pdf>

Stimulus Material

- 8.1 Stimulus material includes any material shown during the course of fieldwork e.g. product profiles, branding concepts, devices, packaging materials.
- 8.2 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.
- 8.3 Within any market research care should be taken to ensure that MR subjects understand when they are providing feedback on draft materials, hypothetical scenarios, assumptions, a product in development or as yet unlicensed.
- 8.4 **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.
- In Finland**, the PIF Code of Ethics states market research **MUST** not focus upon a medicinal product which has not obtained marketing authorisation.
- 8.5 Where required (country requirement or company policy) stimulus materials to be used within market research should be approved by the client company’s medical department prior to use (irrespective of format or finish).
- 8.6 Companies may want to consider the need for respondents to sign some form of confidentiality or non-disclosure agreement if commercially sensitive information is shared with them and the respondent is made aware of the identity of the end client company.
- 8.7 All stimulus materials should be collected at the end of the interview.

Additional ABPI guidelines for stimulus material content and format **for the UK** are detailed within the BHBA’s Legal & Ethical Guidelines <http://www.bhbia.org.uk/guidelines/legalandethicalguidelines.aspx>.

Use of Product Names

- 9.1 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

The use of brand names when researching hospital ‘H’ drugs with patients **in Italy** although not explicitly forbidden would be considered unethical. The **Spanish** Code of Good Practices for the Promotion of Medicines and Interaction with Healthcare Professionals requires that there is no link between the product tested and a company, so product testing should be blinded.

Testing Products

- 10.1 Companies should generally refer to their medical and regulatory departments for guidance on market research surveys that involve testing products.
- 10.2 It is strongly recommended that placebos are used during market research surveys whenever practical.
- 10.3 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 MR 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 MR 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.
http://ec.europa.eu/health/files/eudralex/vol-1/dir_2005_28/dir_2005_28_en.pdf
- 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.
- 10.4 For market research involving medical devices or diagnostics only (i.e. there is no active ingredient involved), if the device is not CE marked, is an implantable device, is to be used outside the approved license or could potentially cause a patient harm (e.g. use of a needle is involved), the commissioning client company's medical department MUST approve the market research approach, confirm whether the Guidelines on Medical Devices (MEDDEV 2.7/4) need to be followed and whether an appropriate healthcare practitioner should be present.
- 10.5 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.
http://www.esomar.org/uploads/public/knowledge-and-standards/codes-and-guidelines/ESOMAR_Codes-and-Guidelines_Mutual-Rights-And-Responsibilities-Of-Researchers-And-Clients.pdf
- 10.6 Clients are fully responsible for all damage or injury caused by materials or products they have provided to researchers for research purposes unless the researcher 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.
- 10.7 As with stimulus material, all products should be collected at the end of the interview.
- 10.8 Adverse Event reporting requirements associated with medical devices should be agreed with the Marketing Authorisation Holder before commencing any market research survey.

M. Recording and Observation of Fieldwork

Personal Data Definition

- 11.1 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.

Consents Required

- 11.2 MR 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. MR subjects MUST always give their consent for this and consent must be recorded.
- 11.3 At the start of fieldwork MR subjects MUST be informed if their personal data is to be passed on to the commissioning client company.

Information to be Communicated to MR subjects when Observed by Client

- 11.4 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, MR subjects MUST be told:
- The name of the recipient company
If naming the recipient company is likely to impact on the integrity of the MR the company name can be withheld until the end of the interview if MR subjects agree. However if MR 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 MR 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 MR 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 MR subject. This is a GDPR requirement.

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

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

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

- Respondents 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.

In Germany Live viewing of non-anonymised fieldwork via one-way mirror or sitting in at the agency's premises (or a sub-contracted specialist facility) is allowed as long as measures are taken to ensure MR subjects are not known and cannot become known to observers. Non-anonymised video footage may not be transferred to the client company to prevent identification of the MR subjects'.

Passing on Recordings without Consent

11.5 Recorded data (audio or video that could identify individual MR subjects) given to clients without MR subject consent **MUST** be anonymised.

When Written Consent is Required

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

When a MR Subject Withdraws

11.7 If a MR 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.

Delayed Viewing of Fieldwork e.g. by video streaming

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

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

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

Listening In or Audio-only recordings

11.9 If it is possible that the MR 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 MR subject has given their informed consent. **In Germany** transferring information that could lead to the identification of the MR subject to the client is prohibited by MR industry guidelines. Listening in to audio only recordings of a simultaneous translation (without the MR subjects' voice) would be anonymous assuming no personal data was revealed, it is always the data controller's responsibility to make sure that anonymity is not compromised.

Client Awareness of Restrictions on use of Recorded Data

11.10 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

11.11 The agency MUST ensure that the country or organisations in those countries, to which any personal data are transferred by them or their sub-contractors have adequate data protection measures in place, particularly outside the EEA.

Observers' Guidelines

11.12 When client observers are introduced, they do not need to be introduced by name. It is sufficient to tell MR 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 MR agency.

11.13 Observers should be informed of their responsibilities towards MR subjects and agree to:

- Withdraw from observing if a MR subject is known to them/recognised to protect the MR subject's anonymity. If an observer knows that they will subsequently have to deal with a MR subject, the attendee MUST also withdraw. However, if MR 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 MR subjects are completely comfortable with this. **In Canada**, observers should be told that if they find they know any of the participants, they must stop observing and notify the researcher. **In Japan**, if a (HCP) MR subject is known to an observer, the observer MUST sign an agreement that they will never disclose information gained while observing, never make any notes, and never use directly or indirectly the information for sales/promotion activities. **In Germany** MR industry guidelines require that the possibility that MR subjects are known to observers should be ruled out before viewing.
- Respect the confidentiality of all information exchanged in interviews/groups.
 - Not record any MR subject's personal data or record any information with the specific aim of establishing the identity of a MR subject.
 - Not make any notes or recordings that could be attributed to a specific MR subject.
 - Not use the information to influence future approaches to a MR subject.
 - Not use information gained whilst observing to amend or build databases.
- Abide by the guidelines for observers. It is good practice to obtain a signed pro forma from all observers agreeing to adhere to these guidelines.

These conditions should apply whether observers are watching a recording or video stream in remote locations or are viewing at the research location.

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

N. Adverse Event Reporting

Based upon the Guideline on good pharmacovigilance practices (GVP), Module VI – Management and reporting of adverse reactions to medicinal products, European Medicines Agency 22 June 2012
EMA/873138/2011

Introduction

- 12.1 EphMRA's Adverse Event Reporting Guidelines detail the scope of market researchers' adverse event reporting responsibilities and the requirements of the process.
- 12.2 Details of suspected adverse reactions that meet the qualifying and minimum reporting criteria should be forwarded by the contracted market research agency and their sub-contractors to the nominated contact within the market authorisation holder that commissioned the market research. This information is assessed by the pharmacovigilance department and if appropriate it will be reported to the regulators as an individual case safety report and/or within a periodic safety update report.

Basis of Guidelines

- 12.3 EphMRA's Adverse Event Reporting Guidelines are based upon legal requirements:
 - Detailed in Directive 2001/83/EC and Regulation (EC) No 726/2004, as regards the collection, data management and reporting of suspected adverse reactions associated with medicinal products for human use authorised in the European Union
 - Interpreted within the European Medicines Agency's Guidelines on good pharmacovigilance practices, particularly volume VI Management and reporting of adverse reactions to medicinal products

Within the European Union, MAHs are legally obliged to report suspected adverse reactions and those adverse events that they consider to be signals. Market research (MR) studies commissioned by pharmaceutical companies (MAHs) but carried out on their behalf on a sub-contract basis by independent MR agencies are subject to the EMAs adverse reaction and event reporting guidelines detailed in module VI and module VII. However if an organisation is conducting an MR programme independently, without being commissioned, financed or influenced by a MAH, the requirements provided in EU pharmacovigilance legislation do not apply. It is the MAH's responsibility to set up contracts with the market research supplier detailing how they would like adverse event reporting to be implemented during the course of the study and the training required.

The term 'adverse event' is used as an umbrella term within this section and refers to adverse events, potential adverse reactions, product complaints and specific reporting situations such as drug interactions.

EphMRA Members' Responsibilities

- 12.4 EphMRA members should understand and adhere to the EphMRA Adverse Event Reporting (AER) Guidelines and ensure others involved in market research (MR) abide by the guidelines too – such as suppliers and sub-contractors as well as colleagues in marketing, sales and national/local market researchers.
- 12.5 The AER Guidelines apply irrespective of which functional area or organisation/department within the marketing authorisation holder (MAH)/pharmaceutical company initiated the work i.e. whether

the work is commissioned by the department responsible for market research, marketing or another function.

Responsibility to MR subjects

- 12.6 All MR subjects whether healthcare professionals or not should be informed at recruitment of the requirement for MAHs to report adverse events that arise during MR.

Impact of Disclosure Requirements

- 12.7 EFPIA disclosure requirements and the US Sunshine Act do not generally require agencies to identify to client companies the names of the healthcare professionals who report adverse events.

Glossary & Terminology

AE	Adverse Event
AER	Adverse Event Reporting
AR	Adverse Reaction
EU	European Union
HCP	Healthcare Professional
ICSR	Individual Case Safety Report
MAH	Marketing Authorisation Holder
MR	Market Research
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance

EMA Guidelines:

“All applicable legal requirements detailed in this Module are usually identifiable by the modal verb “shall”.

Guidance for the implementation of legal requirements is provided using the modal verb “should”.”

Important Background Information

- 12.8 The European Medicines Agency categorises adverse event reports as solicited or unsolicited depending upon their source. With regard to market research sources solicited reports include AEs from MR studies except when social media/digital listening is used, AEs arising from digital listening are classified by the EMA as unsolicited reports.
- 12.9 Adverse events may be collected within Individual Case Safety Reports or as Signals within Periodic Safety Update Reports collated by the marketing authorisation holders’ pharmacovigilance department and forwarded to the regulators.
- 12.10 **Solicited reports** are *“derived from organised data collection systems, which include clinical trials, non-interventional studies, registries, post-approval named patient use programmes, other patient support and disease management programmes, surveys of patients or healthcare providers, compassionate use or name patient use, or information gathering on efficacy or patient compliance.”* The European Medicines Agency (EMA) state that *“safety reports originating from market research (MR) programmes should be considered as solicited reports. A MR programme refers to the systematic collection, recording and analysis by a marketing authorisation holder of data and findings about its medicinal products, relevant for marketing and business development.”*

- 12.11 **Unsolicited reports** include spontaneous reports, literature reports, other sources e.g. lay press and those from the internet or digital media. The EMA states that:
- *“MAHs should regularly screen internet or digital media under their management or responsibility, for potential reports of suspected ARs. In this aspect, digital media is considered to be company sponsored if it is owned, paid for and/or controlled by the MAH*
 - *“If a MAH becomes aware of a report of suspected AR described in any non-company sponsored digital medium, the report should be assessed to determine whether it qualifies for reporting”*
- Consequently AEs arising from the use of social media to gather market research information i.e. digital listening will be unsolicited reports whilst those cited during any other form of online market research, face to face, telephone or postal market research will be solicited reports. This does not make any difference to market research activities.
- 12.12 **Individual Case Safety Report (ICSR)** refer *“to the format and content for the reporting of one or several suspected adverse reactions in relation to a medicinal product that occur in a single patient at a specific point of time. A valid ICSR should include at least one identifiable reporter, one single identifiable patient, at least one suspect adverse reaction and at least one suspect medicinal product.”*
- 12.13 **Signals** are *“information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.”*
- 12.14 ICSRs are forwarded directly to regulators and ICSRs and signals are incorporated into **periodic safety update reports** these are the *“format and content for providing an evaluation of the risk-benefit balance of a medicinal product for submission by the marketing authorisation holder at defined time points during the post-authorisation phase.”*

Source: Module VI – Management and reporting of adverse reactions to medicinal products, European Medicines Agency 22 June 2012
EMA/873138/2011

EphMRA Adverse Event Reporting Guidelines

Scope	EMA Guidelines	EphMRA Guidelines
Scope	<p>Suspected adverse reactions (serious and non-serious) and emerging safety issues associated with medicinal products for human use authorised in the EU.</p> <p>A medicinal product is for:</p> <ul style="list-style-type: none"> – Treating or preventing disease in human beings – Restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis <p>Applicable to medicinal products authorised in the EU but also to any such medicinal products commercialised outside the EU by the same marketing authorisation holder (MAH) All ARs suspected to be related to any of the active substances being part of a medicinal product authorised in the EU.</p> <p>The pharmacovigilance (PV) rules laid down in Directive 2001/83/EC and Regulation (EC) No 726/2004 do not apply to investigational medicinal products and non-investigational medicinal products used in clinical trials conducted in accordance with Directive 2001/20/EC21.</p> <p>Independent of the strengths, pharmaceutical forms, routes of administration, presentations, authorised indications, or trade names of the medicinal product.</p> <p>Where a case of ARs is reported to be related only to a therapeutic class, it is considered incomplete and does not qualify for reporting.</p>	<p>AER Guidelines apply to authorised medicines for human use.</p> <p>AER applies to both prescription and non-prescription bound (over the counter) medicines.</p> <p>AER requirements associated with medical devices should be agreed with the MAH.</p> <p>AEs that relate to any medicinal product for which the drug company is the authorisation holder need to be forwarded. Market researchers are not required to collect events cited for other companies' medicinal products.</p> <p>Serious and non-serious adverse reactions should be included. It is not the market researcher's responsibility to decide what is and is not serious.</p> <p>AEs should be forwarded whether cited in the company's brand or generic name.</p> <p>AEs cited in groups of drugs should not be forwarded.</p> <p>Companies should provide agencies with a list of medicinal products for which they hold the marketing authorisation.</p>
Definition of an Adverse Event	<p>Any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.</p>	<p>The definition of an adverse event is taken from the EMA's Guideline on good pharmacovigilance practices (GVP) Annex I – Definitions 2012.</p> <p>Adverse event is an 'umbrella term' that includes adverse reactions and product complaints.</p>

<p>Definition of an Adverse Reaction</p>	<p>A response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility. Adverse reactions may arise from use of the product within or outside the terms of the marketing authorisation or from occupational exposure. Conditions of use outside the marketing authorisation include off-label use, overdose, misuse, abuse and medication errors.</p> <p>Plus:</p> <ul style="list-style-type: none"> – Suspected or confirmed falsified product or quality defects – Suspected transmission via a medicinal product of an infectious agent – Misinformation in the product information – Use of a medicinal product during pregnancy or breastfeeding – Lack of therapeutic effect . . . unless the reporter has specifically stated that the outcome was due to disease progression – For vaccines , cases of lack of therapeutic effect should be reported – Drug interactions – drug/drug, drug/food, drug device and drug/alcohol <p>Reports of overdose, abuse, off-label use, misuse, medication error or occupational exposure with no associated adverse reaction should not be reported as ICSRs. They should be considered in periodic safety update reports as applicable.</p>	<p>An adverse reaction is directly linked to the medicine i.e. is caused by the medicine, the adverse event may not be.</p> <p>Lack of efficacy whether unexpected or expected needs to be reported unless it is due to disease progression i.e. the drug would have been expected to work but the patient’s disease worsened.</p>
<p>Causality</p>	<p>The definition of an AR implies at least a reasonable possibility of a causal relationship between a suspected medicinal product and an adverse event</p> <p>If the primary source has made an explicit statement that a causal relationship between the medicinal product and the adverse event has been excluded and the receiver (competent authority or marketing authorisation holder) agrees with this, the report does not qualify as a valid ICSR since the minimum information is incomplete.</p>	<p>It is not the market researcher’s responsibility to assign causality</p> <p>AEs should be reported even if the reporter states that there is no link/causal relationship between the event and the drug. This may be the case but the decision not to forward the event can only be taken by the MAH.</p>
<p>Minimum Reporting Criteria</p>	<p>A valid ICSR should include at least one identifiable reporter, one single identifiable patient, at least one suspect adverse reaction and at one suspect medicinal product.</p>	<p>For the purpose of reporting AEs, the minimum data elements for a case are:</p> <ol style="list-style-type: none"> 1. Identifiable reporter 2. Identifiable patient or patients 3. Suspected adverse event 4. Suspected medicinal product.

	<p><u>1. Identifiable reporter</u> One or more identifiable reporter characterised by qualification (e.g. physician, pharmacist, other HCP, lawyer, consumer or other non-HCP) name, initials or address.</p> <p>There are several types of primary sources [reporter]:</p> <ul style="list-style-type: none"> – A healthcare professional is defined as a medically-qualified person such as a physician, dentist, pharmacist, nurse, coroner or as otherwise specified by local regulations. – A consumer is defined as a person who is not a healthcare professional such as a patient, lawyer, friend, relative of a patient or carer. <p><u>2. Identifiable patient</u> One single identifiable patient characterised by initials, patient identification number, date of birth, age, age group or gender. The information should be as complete as possible.</p> <p>Reasonable attempts should therefore be made to obtain and submit the age or age group of the patient when a case is reported by a healthcare professional, or consumer in order to be able to identify potential safety signals specific to a particular population.</p> <p>When collecting reports of suspected ARs via the internet or digital media, the term “identifiable” refers to the possibility of verification of the existence of a reporter and a patient via verifiable contact details (e.g. an email address under a valid format)</p> <p><u>3. Suspected medicine</u> One or more suspected substance/medicinal product</p> <p>Biological medicinal products, the definite identification of the concerned product with regard to its manufacturing is of particular importance. Therefore, all appropriate measures should be taken to clearly identify the name of the product and the batch number</p> <p>MAH responsibilities apply to reports related to medicinal products for which ownership cannot be excluded on the basis of one the following criteria: medicinal product name, active substance name, pharmaceutical form, batch number or route of administration.</p> <p><u>4. Suspected adverse reaction</u></p>	<p>Researchers should identify events based on the information cited, they are not required to probe for missing reporting criteria.</p> <p>THE FOLLOWING GUIDELINE HAS BEEN AGREED WITH THE EMA BUT THE ISSUE OF AER FOR UNIDENTIFIABLE AND UNTRACEABLE PATIENTS IS STILL UNDER CONSIDERATION AND EphMRA IS AWAITING FURTHER GUIDANCE FROM THE EMA If an adverse event is mentioned in the context of a group of patients it is essential to establish that the patients actually exist i.e. they are/were real patients actually seen. Reporters should be able to state how many patients have been impacted if it is suggested there is more than one. If this information is not available, the adverse event does not need to be forwarded. In the UK, ABPI/BHBIA AER guidelines state that AEs without an identifiable individual patient or numbered group of patients still need to be reported.</p> <p>When forwarding AEs arising from the use of social media to gather market research information i.e. digital listening (spontaneous AEs), for both the reporter and patient (it may be the same person) it should be possible to verify the individual’s existence via contact details even if these are not to be used.</p>
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	<p>One or more suspected AR. The report does not also qualify as a valid ICSR if it is reported that the patient experienced an unspecified AR and there is no information provided on the type of AR experienced.</p> <p>Reports, for which the minimum information is incomplete, should nevertheless be recorded within the pharmacovigilance system for use in on-going safety evaluation activities</p> <p>Reports should include the verbatim text as used by the primary source or an accurate translation of it</p>	<p>AEs should be reported even if the details are incomplete:</p> <ol style="list-style-type: none"> 1. Reporter – in MR research there will always be a reporter and it will generally be known if the reporter is at least a HCP or a non-HCP 2. Patient – there should be a patient or a specific number of patients. Patient details should be collected if possible 3. Drug – there must always be a drug for which the company commissioning the MR is the MAH 4. Adverse Event – there must always be an AE of some type even if the detail is sparse <p>Describe the AE as clearly and carefully as possible, try to avoid paraphrasing</p>
<p>Passing on Reporter Contact Details</p>	<p>Whenever possible, contact details for the reporter should be recorded so that follow-up activities can be performed. However, if the reporter does not wish to provide contact details, the ICSR should still be considered as valid providing the organisation who was informed of the case was able to confirm it directly with the reporter.</p>	<p>Researchers must ask the reporter if they are willing to provide their contact details and allow these to be passed to the MAH so that if required PV follow up is possible.</p> <p>Contact details (i.e. personal data) cannot be passed on without consent, explicit consent in the case of patients. When securing consent to transfer personal data to the pharmaceutical company for AE reporting the GDPR requires that the recipient company is identified. As AE reporting is a separate processing operation (to the MR), consent for this may be secured at the end of the interview.</p> <p>In addition, when asking for consent to pass on contact details, it must be clear that the MAH can only use the personal data for AE investigation purposes and reporters must be made aware that they may be re-contacted with regard to the AE by the MAH. AEs can be forwarded without contact details if consent to pass these on is denied. In Germany MR industry guidelines prohibit revealing MR subject identity</p>

		to the client. It may be practical to request that the MR agency facilitates any follow up between the MAH's PV department and the reporter (so protecting the reporter's anonymity) by allowing questions and answers to be passed via the agency with no personal data passed to the MAH.
Consent for Further Follow Up from a Consumer	Attempts should be made to obtain consent to contact a nominated HCP to obtain further follow-up information	Non-HCPs/consumers should be asked if they are willing to consent to supply contact details for the relevant HCP. If they do not consent, the AE should still be forwarded
Duplication of AE Reports	If the primary source may also have reported the suspected AR to another concerned party, the report should still be considered as valid	Even if the primary source/reporter has already reported the AE directly to the authorities or the MAH, it must be reported from the MR
Who Should Forward AEs	Any personnel of the marketing authorisation holder, including medical representatives and contractors.	All employees of the commissioning pharmaceutical company/MAH - market researchers, sales representatives, clinical research associates etc. All organisations and individuals contracted to work (and report AEs events) on behalf of the MAH including MR agencies, MAHs should have a contract in place with all their suppliers Any sub-contractors used by the MR agency e.g. freelance recruiters, interviewers, coders – MR agencies should have a contract in place with all their suppliers
Reporting Timetable	Contextual information: The clock for the reporting of a valid ICSR starts as soon as the information containing the minimum reporting criteria has been brought to the attention of the national or regional PV centre of a competent authority or of any personnel of the marketing authorisation holder, including medical representatives and contractors. This date should be considered as day zero. In practice this is the first business day the receiver becomes aware of the information.	AE reporting forms should be completed and forwarded to the MAH within one business day of the first awareness of the AE. Awareness refers to first knowledge within the normal course of the MR process/project. E.g. For AEs cited within a self-completion online survey, first knowledge will be on review of the data at the DP/analysis stage, in which case it will not be forwarded until after fieldwork.
Reporting Formats		There are two potential AER formats: – AE Reporting Form - generally used when responses are generated or analysed on a MR subject by MR

		<p>subject basis e.g. from one to one interviews or group discussions</p> <ul style="list-style-type: none"> – Tabulations of aggregate data - appropriate when AE data are only reviewed in aggregate so AEs can only be detected at the point of coding or analysis at intervals during fieldwork or at the end of data collection e.g. an online survey <p>The reporting format should be agreed with the MAH at the project start</p>
AE Reporting Form		<p>The MAH should supply the AER form</p> <p>EphMRA provide a standard AER form that can be used</p>
When and How To Complete AER Forms		<p>Complete the AER form at the end of the interview – there is no need to interrupt the interview to fill it in</p> <p>Collect as many details on the form as possible, ideally complete it with the help of the reporter</p> <p>The company should provide an email or fax address to which completed AER forms should be sent</p>
The Format of AE Tabulations		<p>AER tabulations should show:</p> <ul style="list-style-type: none"> – Number of MR subjects citing event – Question base i.e. how many MR subjects answered the question <p>The format should be agreed with the MAH in advance of data processing</p>
Quality Management and Training	<p>Clear written standard operating procedures should guarantee that the roles and responsibilities and the required tasks are clear to all parties involved and that there is provision for proper control and, when needed, change of the system. This is equally applicable to activities that are contracted out to third parties, whose procedures should be reviewed to verify that they are adequate and compliant with applicable requirements.</p> <p>Personnel who may receive or process safety reports (e.g. clinical development, sales, medical information, legal, quality control) should be trained in adverse event collection and reporting</p>	<p>Both client companies and market research agencies should have clear and comprehensive operating procedures in place for the collection of adverse events – these should be exchanged upon project commissioning at the latest and AER responsibilities built into contracts.</p> <p>Training should be undertaken to ensure that all those directly involved in AE reporting have a clear understanding of how to recognise an AE and what action is required</p>

	<p>in accordance with internal policies and procedures.</p> <p>Where the MAH has set up contractual arrangements with a person or an organisation, explicit procedures and detailed agreements should exist between the MAH and the person/organisation to ensure that the MAH can comply with the reporting obligations. These procedures should in particular specify the processes for exchange of safety information, including timelines and regulatory reporting responsibilities and should avoid duplicate reporting to the competent authorities.</p>	
Confirmation and/or Reconciliation Process	<p>When transfer of PV data occurs within an organisation or between organisations having concluded contractual agreements, the mechanism should be such that there is confidence that all notifications are received; in that, a confirmation and/or reconciliation process should be undertaken.</p>	<p>Confirmation and/or reconciliation involves production of a summary of all AEs identified during the project to be 'reconciled' with/checked against the individual AEs received during the MR study ensuring all AEs are accounted for</p> <p>An AE reconciliation form should be completed at the end of each MR study (not at the end of fieldwork) even if no AEs were forwarded and irrespective of whether data collection forms or tables were used</p> <p>Reconciliation form should include:</p> <ul style="list-style-type: none"> – Number of AEs identified (not just reported) – Summary by each AE of MR subject ID, medicinal product (s) and event details
Syndicated Studies	<p>MAHs have no obligations [to collect AEs] if the programme is not commissioned, financed or influenced by them. In this example* GVP VI does not apply, since it concerns only MAHs and Competent authorities in the EEA. However local requirements may be applicable to the organisation who is conducting the programme. You need to check directly with the competent authorities of the Member State where the programme is conducted. Source: EMA Comment to EphMRA</p> <p>* "this example" refers to market research studies that are designed and run independently by a market research agency and the findings then sold to several pharmaceutical manufacturers, so there is no MAH involved during design, data collection or processing.</p>	<p>For syndicated studies e.g. patient diary studies, there is no legal responsibility for the supplier to forward AEs as the supplier is not the legal agent at the time of data collection</p> <p>Responsibility to collect AEs lies with the MAH that purchases the syndicated data, the MAH's market researcher should forward the AE data to the PV department, the supplier may be requested to prepare the data in the appropriate format for the MAH</p> <p>If confidential questions are added to a syndicated survey by a MAH, the data from these questions must be treated in the same way as an ad hoc study i.e. the</p>

		agency should forward AEs generated by these questions
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<p>Longitudinal Patient Databases</p>		<p>Longitudinal patient databases e.g. GPRD (General Practice Research Database) are out of scope</p> <p>The Council for International Organisation of Medicinal Sciences (CIOMS) V suggests that there is no obligation to search through such databases for individual AEs as this will give rise to spurious signals and conclusions however if they are found (deliberately or co-incidentally), they should be forwarded. Data from longitudinal patient databases are different to tabular AE summaries collected from MR as they have not arisen from a defined project and are for multiple uses, not just acquired by an MAH for internal use (unlike commissioned MR)</p>
<p>If You Have Questions</p>		<p>The MAH's PV department is a most important source of guidance on requirements for forwarding AEs</p>

EphMRA Adverse Event Reporting Form – TEMPLATE

MR Agency Information			
Agency name			
Telephone number			
Researchers name			
Date aware of Adverse Event			
Project title/reference number			
MR subject ID/AE number			
Patient Information			
Number of patients			
Availability of patient information	YES	NO	
Age and Gender	AGE	FEMALE	MALE
Pregnant	YES	NO	
Drug and Event Information			
Drug name			
Description of Adverse Event			
Indication/condition for which drug prescribed			
Daily Dose		DON'T KNOW	
Lot/batch number.		DON'T KNOW	
Frequency		DON'T KNOW	
Route of administration/form		DON'T KNOW	
Reported to local regulator	YES	NO	DON'T KNOW
Does reporter think drug caused event	YES	NO	DON'T KNOW
MR Subject/Reporter details			
Reporter/MR subject name			
Reporter type (E.g. doctor, patient)			
MR subject's address/contact information if willing to provide			
	NOT WILLING TO PROVIDE		
I agree to my information being forwarded to [NAME OF COMPANY/MAH] for the purpose of following up on this adverse event report if follow up is necessary			
Willing to be contacted for follow up	YES	NO	
	SIGNATURE		
Doctor's name & address if patient is a MR subject/reporter			

6. Key Research Stages – After Fieldwork

O. Analysis and Quality Control

- 13.1 Researchers and agencies should anonymise or pseudonymise personal data as soon as possible during the MR process.
- 13.2 Researchers must when requested by clients allow independent checks on the quality of data collection.

P. Storage and Security

Consent for Storage of Personal Data for Future Use

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

Storage Duration

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

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.

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

Security

- 13.6 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.
- 13.7 The data disposal method should be appropriate to the sensitivity and confidentiality of the data.
- 13.8 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.
ESOMAR Guide on Passive Data Collection, Observation and Recording

Q. Reporting Market Research

- 13.9 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.
- 13.10 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 MR subject.
- 13.11 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.

R. Publishing Market Research

- 13.12 The client should not publish any of the results of the survey without the approval of the agency unless otherwise agreed in advance.
- 13.13 **In Spain**, market research studies not published in renowned scientific/medical publications (i.e. NEJM, Lancet, etc.), cannot be used as references for prescription medicines promotional materials.
- In Turkey**, the AIFD Code of Good Promotional Practice and Good Communication 2015 5.2, states that the use of IMS grid sales data in promotion does not conform to the Code.
- 13.14 Researchers should check any client-prepared materials prior to publication to ensure that the research results are not misleading.
- 13.15 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.
- 13.16 **In the USA**, CASRO and MRA members are obliged to disclose the:
- Sponsor of the study
 - Description of the study’s purpose
 - Name of the research organisation conducting the study
 - Method of data collection
 - Date(s) of data collection
 - Sampling frame, method and size
 - Exact wording of the questions
 - Calculated margin of error for quantitative studies

CASRO Code of Standards and Ethics for Survey Research, <http://www.insightsassociation.org/issues-policies/casro-code-standards-and-ethics>

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.

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

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

7. Researchers' Responsibilities by Research Approach

S. Face to Face Methodology

14.1 It is good practice for the interviewer to provide an identity card to the MR subject.

T. Telephone Methodology

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

Naming the Agency/Researcher

15.1 The interviewer MUST give the name of the agency that he/she represents and MUST give their own or an agreed contact name.

Do not call lists

15.2 Do not call lists specific to market research must be respected.

Special Precautions When Contacting Mobile Phones

15.3 Researchers should take special care when contacting MR subjects via mobile phones (whether by voice, text or email), with regard to MR 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 MR subject should be told the likely length of the interview.
- It may be more convenient to arrange an appointment to call back at a different time or via a land line.
- Researchers should try to establish as early as possible if the number to be contacted / contacted is that of a mobile or a fixed-line telephone.

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

Use of Unsolicited Texts for Recruitment

15.4 ESOMAR advises against the use of unsolicited text messages to recruit market research study MR subjects and provides a '*Summary of regulations covering unsolicited contacts (business to consumer)*' May 2013, this is available on the ESOMAR website.

Use of Apps

15.5 You must have a lawful basis e.g. MR subject consent for the use of an app and MR 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. See also 17.7 and for further details see ESOMAR's Guideline for Conducting Mobile Market Research.

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

Country Specific Guidance

- 15.6 Regulations in force in **Canada** could potentially establish legal liability for researchers contacting potential MR 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.
- 15.7 **In Germany and the UK** the use of predictive/auto-diallers is restricted. **In the USA** they are permitted only if the MR 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.
<https://www.mrs.org.uk/pdf/2012-02-23%20Regulations%20for%20Predictive%20Diallers.pdf>
- 15.8 **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
- 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.
- 15.9 **In the USA** the CASRO 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’).
- 15.10 **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, CASRO members maintain internal do-not-call lists of those individuals who have specifically requested not to be contacted by that company for participation in survey research.
- FCC Regulations (October 2013), permit market research calls made to mobile phones using an auto-dialler only with the “prior express consent” of the intended recipient to receive such calls.
- 15.11 **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).

U. Ethnographic/Observational Approaches

Definitions

- 16.1 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 MR subjects are openly observed (participant observation) or covertly or indirectly observed (non-participant).
- 16.2 Images of people on film and audio recordings of them would be considered as personal data under Data Protection legislation.

Guidelines

- 16.3 When conducting ethnographic market research researchers are advised to:
- Inform MR 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 MR subjects of the extended nature of ethnographic research at the point of recruitment before they agree to participate. Timings should be clear.
 - Inform MR 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

- 16.4 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.

<https://www.mrs.org.uk/pdf/2014-09-01%20Qualitative%20Research%20Guidelines.pdf>

http://www.esomar.org/uploads/public/knowledge-and-standards/codes-and-guidelines/ESOMAR_Codes-and-Guidelines_Passive_Data_Collection-Observation-and-Recording.pdf

V. Online & Mobile Market Research

Definitions

- 17.1 Online or internet research refers to research in which a MR 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

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.

- 17.2 An online ‘access panel’ is defined as a sample of potential MR 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 at 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.
- 17.3 A MR subject’s email address or other personal identifiers (e.g. screen or user name or device identifier) is personal data where it refers to an individual and therefore needs to be protected in the same way as other identifiers. A person’s digital image is personally identifiable data. Geo-location data may be considered personal data too.
- 17.4 **In the UK** market research emails are not defined as commercial communications within the 2011 Amended Privacy and Electronic Communications Regulations. Consequently clients can forward customer email addresses to agencies (for recruitment purposes), unless the client has included market research in their standard data protection opt out policy.

Informed Consent

- 17.5 If relying on informed consent you must provide an easy way for MR subjects to supply and withdraw it.
- 17.6 MR subject consent is required for the installation and use of software such as an app and MR 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

- 17.7 Researchers MUST post a privacy policy statement, sometimes referred to as a privacy notice. The statement should be easy to find, easy to use and understand, including by children when appropriate.
- 17.8 Links to data protection; privacy policy or cookie consent statements MUST be given at the start of the market research. This will ensure that should MR subjects fail to complete the exercise for any reason their rights are protected.
- 17.9 If a repeat or follow-up survey is intended, a lawful basis for storage of their contact data e.g. consent is needed. The MR 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.
- 17.10 When emails are sent in batches, MR subjects' email addresses MUST be kept confidential, so for instance blind copying should be used.

MR Subject Costs

- 17.11 MR subjects should be alerted to any costs they may incur e.g. online charges and recompensed appropriately for these.

Researcher or Agency Contact Details

MR 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

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

17.13 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

- 17.14 Cookies store specific information about online browsing. EU legislation states that a cookie can be stored on a user's computer, or accessed from that computer, only if the user "has given his or her consent, having been provided with clear and comprehensive information". So the use of cookies MUST be disclosed, as well as a clear description of the data collected and the uses to which it will be put – this MUST be easily accessible - and consent may be required (depending upon national legislation.) and whether personal data is collected or not. ESOMAR provides a Practical Guide on Cookies

Interview Duration

17.15 MR 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

17.16 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

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

http://www.esomar.org/uploads/professional_standards/guidelines/ESOMAR-Codes&Guidelines-Legislative-issues-unsolicited-contacts.pdf

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

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.

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 therefore prior consent is not required. If, however, under the pretense of market research the intention is to sell something, this exception does not apply.

In the USA the Federal CAN SPAM Act and CASRO's mandatory Code of Standards requires prior consent from individuals to be contacted via their email addresses. CASRO'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').

Identification of the Client

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

Active Self-Selection of MR subjects in Germany

17.19 **In Germany**, the ADM Standards for Quality Assurance for Online Surveys state that participants within online surveys MUST be actively selected (i.e. they MUST opt-in) as opposed to passive self-selection. *ADM Standards for Quality Assurance for Online Surveys 2007*

17.20 Measures should be in place to validate the identity of MR subjects (to avoid surrogate MR subjects) and to check the quality of responses (e.g. to identify cursory or random response patterns).

Use of Apps

The AMSRS (Australia), the MRS (UK) and CASRO (USA) also provide the following guidelines, drawn from the Draft Mobile Research Guidelines August 2013:

<https://www.mrs.org.uk/pdf/2013-08-30%20Draft%20AMRS%20CASRO%20MRS%20Mobile%20Research%20Guidelines.pdf>

17.21 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

17.22 MR 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.

Consent for downloading software to be used for market research purpose should be sought and a means provided to address questions.

ESOMAR provides example disclosure statements within its Guidelines for Online Research 2011 and details a series of 15 'Unacceptable Practices' that researchers must forbid or prevent.

<https://www.esomar.org/what-we-do/code-guidelines/esomargrbn-online-research-guideline>

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

For the USA CASRO provides detailed guidelines with regard to the use of active agent technology within its Code of Standards and Ethics

Online Access Panels

- 17.23 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 MR 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.
- 17.24 ESOMAR provides a series of guidelines on internet access panels, covering panel recruitment, management, monitoring, maintenance and privacy/data protection, and a battery of 26 Questions to help research buyers. More details can be found within these guidelines and the question battery can be found at *ESOMAR Guideline for Online Research Aug 2011*.
- 17.25 ESOMAR are also developing joint guidelines with the GRBN for Online Sample Quality which provide guidance on the operational requirements for providing online samples for market, research.
<https://www.esomar.org/uploads/public/knowledge-and-standards/codes-and-guidelines/ESOMAR-GRBN-draft-Online-Sample-Quality-Guideline-April-2014.pdf>

W. Social Media

Definition

18.1 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).”

Accessing Social Media Content including Website Terms and Conditions

18.2 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

18.3 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

- 18.4 Without the contributor’s consent (obtained as part of the terms of use or directly) or another lawful basis only anonymised data can be reported. Anonymised data should not reveal any personally identifiable information.
- 18.5 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.
- 18.6 Quotations containing personal data can only be provided to the client if you have a lawful basis for this e.g. the contributor has given their consent for this and it has been made clear that they will not be subject to promotion as a result of this. **In Germany**, MR subject identity must remain anonymous and MR subjects cannot be asked to waive their right to confidentiality
- 18.7 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.

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

Active market research i.e. engaging with participants

- 18.8 Consent from the site/service owners and **contributors/users** MUST be given.
- 18.9 Researchers MUST declare their presence, they MUST NOT represent themselves as anything other than market researchers.
- 18.10 Contributors **should** be told the identity of the research organisation, purpose of the market research, what sort of data will be collected, how their comments will be used and who will have access to it. If processing personal data you must meet data protection requirements.
- 18.11 Contributors should be provided with contact information for the researcher or research agency. If you are processing personal data you must identify data controller(s), recipients of personal data and the source of the personal data (if it wasn't obtained directly from the individual).
- 18.12 Researchers should publish a privacy policy/notice on their website.
- 18.13 Online space created specifically for MR 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

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

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

8. MR Subjects' Rights by MR Subject Type

X. Patients

Patients

19.1 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 MR subjects with regard to the safety of a product.
- Encourage members of the public/patients to ask their doctor to prescribe a product.
- Offer advice on the specific therapy area under discussion.

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

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

19.3 **In Greece**, the SfEE's Code of Ethics states (within the English translation) that:

- "The data from HCPs referring to patients shall be collected and delivered fully anonymized and in aggregate form."

Y. Simulated Consultations

19.4 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.

19.5 There is no restriction upon the use of protected health information if it has been de-identified. There are two ways to de-identify data. The first method is to remove all identifiers such as:

- (A) Names
- (B) All geographic data, including street address, city, county, part or all of the postal code
- (C) Elements of dates (except year) directly related to an individual, including birth date, admission date, discharge date, date of death; and identifying ages e.g. those over 89;
- (D) Telephone numbers;
- (E) Fax numbers;
- (F) Electronic mail addresses;

- (G) Social security numbers;
- (H) Medical record numbers;
- (I) Health plan numbers;
- (J) Account numbers;
- (K) Certificate/license numbers;
- (L) Vehicle identifiers and serial numbers, including license plate numbers;
- (M) Device identifiers and serial numbers;
- (N) Web Universal Resource Locators (URLs);
- (O) Internet Protocol (IP) address numbers;
- (P) Biometric identifiers, including finger and voice prints;
- (Q) Full face photographic images and any comparable images; and
- (R) Any other unique identifying number, characteristic, or code

The second option is to have a qualified statistician determine that the risk is very small that the information could be used to identify the individual.

<https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/>

Z. Vulnerable MR subjects

Definition

20.1 Vulnerable MR 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 MR subjects because of their age, physical or mental health. A vulnerable MR subject could be someone who is HIV positive or has cancer, a psychiatric illness or is physically handicapped.

What to Consider When Interviewing Vulnerable Patients

- 20.2 If the MR 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?
- 20.3 When a potentially sensitive issue has been discussed with a vulnerable MR subject members may provide information or relevant helpline information.

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

AA. Children and Young People

Definitions

21.1 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. **In Canada**, a child is to be defined as under the age of 14, a young person as aged 14-17. **In Mexico** all those under 18 are considered children. **The UK** MRS Code of Conduct defines a child as a person under the age of 16 and 'young people' refers to those aged 16 and 17 years. **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.

Consents Required

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

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

In Germany, children under 11 **MUST** have consent (oral) to participate from their legal representative. With children aged 11-13, the agency may establish if the child has the necessary cognitive faculty and not seek consent but if they are under 14 years, the interview should not be conducted without the knowledge of an adult present in the home. In addition, consent is always needed if personal data relating to adults will be asked of the children at recruitment or during the interview.

In Mexico, written consent from the responsible adult must be obtained for all market research with MR subjects under 18 years of age.

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

21.3 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.

21.4 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.

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

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

Online Market Research with Children

21.7 EphMRA recommend that online research is not conducted with children under the age of 14.

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

21.9 **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. <http://business.ftc.gov/documents/Complying-with-COPPA-Frequently-Asked-Questions>

21.10 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

21.11 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.

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

Researchers' Responsibilities

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

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

21.15 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.

21.16 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.

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

Incentives

21.18 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

21.19 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.

21.20 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

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

<https://www.mrs.org.uk/pdf/2014-09-01Children%20and%20Young%20People%20Research%20Guidelines.pdf>

BB. Opinion Leaders, Clinical Trial Investigators and Advisory Board Members

- 22.1 When recruiting MR 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.
- 22.2 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 MR 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.

CC. Physicians and Other Healthcare Professionals

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

DD. Payers and Influencers

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

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

9. Complaints and Grievance Procedure

- 25.1 Breaches of the Code of Conduct and complaints will be investigated in the first instance by EphMRA's Ethics Group, and if necessary concerns/complaints upheld by EphMRA may then be referred to the appropriate regulatory body, following which disciplinary measures may be taken by these organisations.
- 25.2 If the Data Protection Directive is breached, action can be taken by the appropriate body in the relevant country e.g. the Information Commissioner's Office in the UK.

Glossary of Key Terminology

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

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

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

Anonymity has two interpretations:

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

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

Client – Any individual or organisation that commissions (including requesting or subscribing) all or part of a market research project.

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

Consent – The freely given and informed agreement by a person to take part in the market research and the processing of his/her personal data

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

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

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

Data subject – any individual whose personal data is used for market research.

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

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

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

Identity – The identity of a MR subject includes, as well as his/her name and/or address any other information which offers a reasonable chance that he/she can be identified by any of the recipients of the information.

Interview – Any form of contact with a MR subject to collect information for market research purposes.

Interviewer – The person who collects data from MR subjects for market research purposes.

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

MR 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 respondent and participant.

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

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

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

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

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

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

Record – Defined as any brief, proposal, questionnaire, MR 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 MR subject and the research results

Recruiter – The person who identifies and invites MR subjects to take part in a market research project.

Researcher – An individual or organisation carrying out, or acting as a consultant on, a market research project, including those working in client organisations.

Secondary market research – Involves collecting and using data that already exists. This data is then re-used and re-analysed, so it is data already gathered for one use that is then utilised for another purpose.

Sensitive Data – Defined as personal information covering the racial or ethnic origin of the MR subject; their political opinions; religious beliefs of a similar nature; whether he/she is a member of a trade union; their physical or mental health or condition; sex life; the commission or alleged commission by him/her of an offence or any proceedings for an offence committed and the outcome.

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

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

Stimulus material – Material shown or referred to or read out to a MR subject during fieldwork

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

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

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

Walled garden is an 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.

Sources

Legislation Supporting The Code of Conduct

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- Telecommunicatie wet
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- CGR Uitwerking Normen Gunstbetoon
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Appendices

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

Pro Forma 1 – Recruitment Agreement

Recruitment Agreement TO BE USED IN CONJUNCTION WITH A RECRUITMENT SCRIPT THAT DETAILS THE MR TERMS	
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:
MR Subject Agreement and Signature	
<p>By signing below/clicking on the box below/returning this email (AMEND AS APPROPRIATE)</p> <p>I consent to <agency name> collecting and using the information about me that I voluntarily provide for the purposes of market research YES NO</p> <p>I have read, understand and agree to the terms described. YES NO</p> <p>OTHER CONSENTS MAY NEED TO BE ADDED</p>	
Signature:	Name (please print)
MR Subject Code Number	
Code Number	

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	
<p>I confirm that the information I have given during the course of this interview/group discussion represents my views on the subject matter.</p> <p>I confirm that I have received the incentive detailed above in appreciation for my contribution to the project.</p>	
MR Subject Signature	
Signature:	Name (please print)
MR Subject Code Number	
Code Number	

MR 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	
<p>I understand that <u>the company that commissioned this market research study</u></p> <p>_____</p> <p>(name of recipient organisation(s) may or may not be required will: DELETE AS APPROPRIATE</p> <ul style="list-style-type: none"> – 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) <p>I understand that the purpose(s) of the company having access is:</p> <p>_____</p> <p>_____</p> <p>The people in the company who will listen to or view the recordings will be in the following functions/roles:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>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.</p> <p>I understand that I can withdraw my consent at any stage.</p> <p>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</p>	
Signatures	
I have read, understand and agree to the terms above.	
MR Subject Signature:	Name (please print)
Agency Signature:	Name (please print)
MR Subject Code Number	
Code Number	

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	
<p>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):</p> <p>_____</p> <p>_____</p>	
<p>The only people in the company who will listen to or view the recordings will be in the following functions/roles:</p> <p>_____</p> <p>_____</p>	
<p>And the recording(s) will be in the secure care of: _____</p>	
<p>On behalf of the commissioning client company I can confirm that:</p> <ul style="list-style-type: none"> – 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 recording 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)

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 respondents. 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 MR subject is known to them or recognised to protect the MR subject's anonymity. If an observer knows that they will subsequently have to deal with a MR subject, the attendee MUST also withdraw from observing. However, if respondents 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 respondents 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 MR subject's personal data or record any information with the specific aim of establishing the identity of a MR subject.
- Not make any separate identifiable notes or recordings that could be attributed to an individual MR subject.
- Attempt to influence how any MR subject is approached in future for sales/promotion.
- Not use information gleaned from the observation to amend or build databases.



CODE of CONDUCT

August 2018