EphMRA

European Pharmaceutical Market Research Association

# CODE *of* CONDUCT *2016*

Includes:

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

# EphMRA CODE *of* CONDUCT *2016*

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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 products, biologics, medical devices and diagnostics (available with or without prescription).

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

**Geographic Scope**

1.3 The Code provides international guidelines, although its development has focused upon - Brazil, 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 national law.

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 is 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. Respondents 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 respondents 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. Respondents MUST be treated fairly and reasonably, with care and courtesy.

V. Respondents 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 not excessive.

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 data protection and privacy legislation.

VIII. There MUST be no unauthorised or unlawful processing, loss, destruction or damage to personal data.

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

## B. What Constitutes Market Research

**Market Research**

3.1 Market research is the systematic gathering and interpretation of information about individuals or organisations using the statistical and analytical methods and techniques of the applied social sciences to gain insight or support decision making. The identity of respondents will not be revealed to the user of the information without explicit consent and no sales approach will be made to them as a direct result of their having provided information.
*Definition of market research contained in the ICC/ESOMAR International Code 2007*

3.2 Market research is not a commercial communication or a selling opportunity.

3.3 Market research has no interest in the individual identity of respondents.

3.4 Direct action MUST NOT be taken in relation to named individuals or organisations as a result of market research (except following up adverse events when permitted).

3.5 Market research is defined by the objective(s) and the approach, not by the title of the work or the role of those commissioning the work.

**Market Research, Ethics Approval and Non-Interventional Research**

3.6 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**).

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

EFPIA Requirements

EFPIA 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

3.8 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 generalizable* to the population?

   * Generalizable 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.
http://www.hra.nhs.uk/documents/2013/09/defining-research.pdf

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 research[7] may be undertaken by professional market researchers on behalf of pharmaceutical or medical device companies. Where such research is conducted by professional market researchers in accordance with the Legal and Ethical Guidelines issued by the British Healthcare Business Intelligence Association (BHBIA), it does not require REC review except where otherwise required by law"*

Key Differences

3.9 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 pharmacokinetics; market research is carried out for a commercial purpose i.e. to investigate market behaviour and opportunities, 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. Patient data used for clinical/medical research purposes involves the direct handling of patient charts by investigators/CROs.

The distinction between market research and non-interventional research applies whether the market research involves prospective or retrospective patient data.

3.10 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 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**

3.11 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 organization
- 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**

3.12 When researchers are fulfilling their role as researchers they MUST NOT conduct other non-research activities without the prior informed consent of respondents. **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**

3.13 The collection of data to directly create sales or influence the respondents' opinions MUST NOT be presented to respondents 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 respondent are given
- Guide/questionnaire and stimulus design is balanced
- There is no unnecessary use of 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
- Respondents 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**

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

**Client and Agency**

3.15 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 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

3.16 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 respondents 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 respondents' personal data to the client without the explicit consent of the respondents. **In Germany** MR industry guidelines state that respondents 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 respondent consent to override this is prohibited too.

## C. Data Protection and Privacy

**Definition of Personal Data**

3.17 The 1995 EU Data Protection Directive covers the collection of data relating to an identifiable person, the Act on the Protection of Personal Information covers the collection of data relating to an identifiable person in Japan. This data is referred to as personal data or personally identifiable information (PII). 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.

An IP address might constitute personal data in combination with other identifiable data but there is no international consensus about the status of IP addresses (which can generally identify a unique computer, but may or may not identify a unique user). If national law/regulations classifies IP addresses as personal data and it is not possible to differentiate between those IP addresses which are linked to an individual and those that are not, all the information collected should be treated as if it were personal data. **In Germany** an IP address is considered by law to be personally identifiable information. **In the Netherlands** this is the case if an IP address can be traced back to a unique user.

**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.

3.18 Personal data covered by the Data Protection Directive includes data "be it alphabetical, numerical, graphical, photographical or acoustic. It includes information kept on paper, as well as information stored in a computer memory by means of binary code, or on a videotape, for instance. In particular, sound and image data qualify as personal data from this point of view, insofar as they may represent information on an individual." (Article 29 DP working party opinion on the concept of personal data of 20 June 2007) Personal data includes video-streams (relayed live or delayed and non-anoymised 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.

3.19 Once all identifiers linking data to a respondent have been removed then it is no longer personal data (it has been anonymised) and is not covered by the Data Protection Directive. Researchers may use a unique identifier (e.g. a serial number) to identify a respondent (a process referred to as pseudonymisation) but the file linking personal data to the unique identifier MUST be stored entirely separately from the anonymised respondent data.

**Definition of Processing of Personal Data**

3.20 The processing of "*personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life*" is forbidden unless one or more of the exceptions specified in the Directive have been met. The most important of these exceptions, in the case of market research is where the respondent has given his/her explicit consent to the processing of such data. Explicit consent refers to a respondent's specific and unambiguous agreement based upon adequate information (see Section 8, Informed Consent).

The 'processing' of personal data includes the collection, recording, organisation, storage, alteration, retrieval, use, disclosure, dissemination, alignment or combination, blocking, erasure or destruction, of personal data.

**Security**

3.21 Researchers are responsible for the safe handling, processing, storage and disposal of market research and personal contact data.

3.22 Adequate precautions MUST be taken to protect personal data, any sensitive data and confidential information against unauthorised access. This would include using the appropriate technologies to protect data stored on websites or servers and when data is transferred e.g. reliable encryption systems, firewall and user identification and password access.

3.23 In addition to Data Protection and 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**

3.24 It is good practice for researchers to keep copies of e-mails and other documents received from respondents agreeing to, or restricting, the use of or access to their personal information. This is a legal requirement in some countries, amongst others, all European Union member states.

**Protection of Personal Data when Transferred**

3.25 Personal data is protected by the provisions of the Data Protection Directive even when taken out of the country where the respondent lives.

3.26 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 contractual 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) – For further information on these see:
http://ico.org.uk/~/media/documents/library/Data_Protection/Detailed_specialist_guides/model_contract_clauses_international_transfers_of_personal_data.ashx

3.27 **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 respondent MUST be made aware if their personal data is to be transferred to a foreign customer and give a written consent to this.

**Respondents' Rights to Their Personal Data**

3.28 Respondents MUST be made aware that they can ask at any time to know what personal data about them are currently being held and for these to be amended or destroyed.

3.29 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). Respondents and those processing personal data must be aware of these, respondents through the data privacy disclaimer.

**Data Localisation Law in Russia**

3.30 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. So 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**

3.31 **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 authorization. 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**

3.32 Members MUST ensure that respondents give their informed consent before information is collected from them.
*"Respondents' 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

ESOMAR state that consent must be:

- Free (voluntary and able to be withdrawn at any time);
- Specific (relating to one or more identified purposes); and
- Informed (in full awareness of all relevant consequences of giving consent).

http://www.esomar.org/uploads/public/knowledge-and-standards/codes-and-guidelines/ESOMAR-draft-Data-Protection-Checklist-September-2014.pdf

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.

3.33 Information detailing an individual's physical or mental health is classified as 'sensitive personal data' under the Data Protection Directive and requires explicit consent for its use.

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

3.35 Informed consent guarantees respondents the right not to participate and the right to withdraw from the interview at any time. This right MUST be made very clear to children.

**Confidentiality & Anonymity**

3.36 It MUST be clear to respondents 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.

3.37 Respondents' anonymity MUST be strictly preserved. It is important to note that withholding a respondent's name is not necessarily sufficient to protect their anonymity especially when respondents 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

3.38 Researchers MUST ensure that information identifying the respondent (e.g. recruitment questionnaires, attendance lists) is not passed to the client without the respondent's explicit consent. Requesting consent to pass on respondent personal data to the client (and consequently passing on personal data) is always forbidden **in Germany.**

3.39 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**

3.40 The respondent's right to confidentiality can be waived by the respondent if specific consent has been sought and granted providing respondents 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 asking respondents to waive their anonymity/confidentiality.

**Separating Personal and Research Data**

3.41 **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**

3.42 Physicians have a duty of confidentiality towards their patients. Information about a patient may be obtained for market research from patient records without patient authorization 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 authorization.

# 4. Respondents' Rights at Key Research Stages - Before Fieldwork

## E. Approval and Registration of Proposals Prior to Fieldwork

4.1 **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/medicine
- 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.

4.2 **In Sweden**, article 42 of 'Ethical Rules for the Pharmaceutical Industry in Sweden' requires members of LIF (the Swedish trade association for the research-based pharmaceutical industry) and FGL (the association representing the manufacturers of generic pharmaceuticals in Sweden) to enter into a central database details of market research to be conducted with healthcare professionals in Sweden.

So the commissioning company - if they are LIF members - MUST record the following information:

- Timeline
- Commissioning pharmaceutical company (incl. contact person)
- Market research agency (if appropriate)
- Short description of the survey
- Payment to participating doctors

This information MUST be logged no later than the day it was sent into the field.

If a market research study is commissioned by a parent company without the knowledge of the Swedish affiliate the study does not have to be registered.

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. 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. If a sub-contractor is employed at short notice after the study has started the client should be informed as soon as practical.

## G. 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 Respondents**

4.6 Researchers should manage and monitor the frequency with which potential respondents 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).

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 require the HCPs prior consent, and if these details are passed to another contractually linked party.

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.

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.

If the list contains information not in the public domain, those listed MUST give consent for their personal data to be held and told why their personal data is being held.

**Anonymity of Respondents 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 Respondents 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 respondents. The source of the list MUST be revealed to potential respondent(s) at an appropriate point in the interview, if it is requested. **In Germany** MR industry guidelines state that respondents MUST be told the client company's identity if the client company supplied their name. This can be given at the end of the interview rather than the beginning, but it MUST be given. **In Finland, a r**esearcher MUST NOT disclose the identity of the sponsor (unless legally required to do so) to any third party without the consent of the sponsor.

**Correcting Listed Information**

4.11 If list details are missing or incorrect, the supplier of the list may be told this but corrected details cannot be passed back to the list supplier to update their databases without specific consent. However it is allowable to pass back the personal details of those who have:

- Died or moved away – so they may be removed from the list
- Asked that their details should be marked 'do not contact' or removed from the list
- Agreed to be re-contacted for specific follow up

**Adding Personal Data to a Database**

4.12 Personal data can be added to the database only if the respondent is told of this intention at the time of data collection except **in Germany**. Respondents 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 respondent 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 Respondent Details**

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

## H. Recruitment

**Physician Recruitment of Patients**

4.14 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 issueing a written rather than a face to face invitation.

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

4.16 **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).

**Snowballing – Respondent supply of Potential Respondents' Names**

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

**Recruitment – Information that MUST be Communicated**

4.18 At recruitment respondents MUST be told:

- Type of organisation sponsoring the market research e.g. a pharmaceutical company
- Subject and the purpose of the market research
- If there is to be observation and/or recording, what sort and types of observers
- Contact details - Name of the researcher, recruiter or research or fieldwork agency , telephone number or email address as appropriate
- Length of the interview
- Of their rights – confidentiality, anonymity, that they can withdraw or withhold information at any time
- What will happen to their data (including personal data) and how it will be used
- Incentive offered – both the nature and the rate of remuneration.
- If the individual healthcare professionals will become known to the commissioning client company the need for disclosure should be explained and consent to pass on their personal data for this purpose requested (see section 4.25 for further detail)
- Healthcare professionals MUST be informed of the need to report adverse events uncovered during the study where this need exists. 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.bhbia.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 respondent, or a source for it given (i.e. hyperlink). Respondents must consent to the terms of the privacy disclaimer.

4.19 If the potential respondent/respondent requests the name of the sponsoring client it is not necessary to provide this information unless the sponsoring client company provided the list from which the potential respondent/respondent's name/contact details have been drawn. The requirements for naming the client when observation and recording are taking place are detailed at 11.4.

4.20 In **Germany**, the FSA Code recommends to members that employer permission (Dienstherrengenehmigung DHG) is sought and granted for healthcare professionals employed in public entities to participate in market research. There is no over-arching legal requirement for a DHG, however if you have to include federal civil servants (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 respondents 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.

**Scheduling of Fieldwork Appointments**

4.22 **In Germany, Italy, Norway and Sweden,** the German market research associations, 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*

**Recruitment Agreements and Disclosure**

4.23 EFPIA members and members of EFPIA-affiliated associations MUST document an agreement between agency or client company and the healthcare professional respondent 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

When written agreements are required, the following information MUST be given and agreed:

- Subject and purpose of the market research discussion
- Methodology and approach
- Location, duration of fieldwork
- Date and time of fieldwork
- Incentive offered – both the nature and the rate of remuneration.

Records of the agreement MUST be kept in line with data protection and privacy legislation records as well as relevant market research guidelines (assuming they contain 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** 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 BHBIA states that to conform to Clause 20 of the ABPI's Code of Practise 2014, 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 BHBIA Guidelines.
http://www.bhbia.org.uk/guidelines/legalandethicalguidelines.aspx
http://www.pmcpa.org.uk/thecode/Pages/default.aspx

Disclosure Requirements

4.24 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 http://transparency.efpia.eu/the-efpia-code-2

When disclosure is required

4.24.1 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 respondents MUST be disclosed**, whether they've paid them directly or indirectly via an agency. This information will be made publicly available.

4.24.2 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 respondents do not consent to their personal data being used for disclosure they may still participate in the MR.

When disclosure is not required

4.24.3 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 respondent is recognised (and identified) by client company personnel, disclosure may not be required.

4.24.4 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

4.24.5 EFPIA have provided a 'Model of a Standardised Template' – the suggested reporting format for disclosure data: http://transparency.efpia.eu/EFPIA%20DISCLOSURE%20CODE%20Schedule%202%20Template%20-%2013%20Template.pdf EFPIA country associations may provide their own template based upon the EFPIA one.

4.24.6 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

4.24.7 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

4.24.8 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

4.24.9 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

4.24.10 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

4.24.11 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
- Respondents' agreement or refusal must be recorded.

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.

4.25 **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 respondents MUST be informed of the processing of their personal data
    - This applies whether or not the client company is aware of respondent 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 Oct and for July to Dec data by 1 April.

**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. Whilst a reporting template does exist and is available on the ASOCs website, ASOCs, SYNTEC and the CNOM are currently planning to develop a revised framework to facilitate more streamlined reporting. This simplified procedure is currently being examined by the CNOM's legal department.
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 http://www.ephmra.org/Country-News

4.26 **In the USA** generally speaking **t**he federal Sunshine Act does not include mandatory disclosure of survey incentives made by drugs 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 respondents' 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.casro.org/news/137727/Physician-Payment-Sunshine-Act-Alert.htm

For further details upon US state Sunshine laws see:
https://www.ama-assn.org/resources/doc/washington/state-sunshine-laws-chart.pdf

**Re-contacting Respondents**

4.27 Informed consent requires that if it is necessary to contact a respondent again to ask further questions (other than for quality control purposes), consent for re-contact MUST be sought at the time of the recruitment interview or during the interview; even if only simple clarification is needed. When children are researched consent for re-contact should be sought from the responsible adult and the child separately.

4.28 Respondents 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 respondents is done by means of a code number.
*Guideline on the Treatment of Addresses in Market and Social Research _Aug 2009 https://www.adm-ev.de/index.php?eID=tx_nawsecuredl&u=0&file=fileadmin/user_upload/PDFS/R07_E.pdf&t=1448018843&hash=ceb28af88da80de2d73eb177b42c0da48254a5e5*

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 counties 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 and explicit 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.

When transferring data outside of the EEA you must comply with all data protection principles. Fair and lawful processing will in most cases require you to inform individuals about transfers of their transfers of their personal data to third parties overseas.

## I. Incentives

**Incentives**

4.31 An 'incentive' is any benefit given to a respondent 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 respondent 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, respondents' personal data MUST NOT be accessible to company personnel outside the research team.

Respondents 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 a specific task or passing of 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.

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 authoriteit, 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 respondent 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 http://www.ephmra.org/Ethics

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

4.40 Disclosure requirements for incentives are detailed within 4.25, 4.26 and 4.27.

**Incentives that are Not Allowed**

4.41 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 respondent 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**

4.42 With regard to free prize draws, i.e. a draw where prizes are allocated by chance, with no payment to enter, respondents 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.

4.43 In **Mexico**, the Secretary of Governance is responsible for authorizing 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.

4.44 '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**

4.45 The personal data of respondents eligible for incentives are confidential, so cannot be passed to clients without consent, this consent MUST NOT be linked to receipt of an incentive.

**Storing Incentive Details**

4.46 **In Germany and in Italy** tax laws make it necessary to store the address data of respondents 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. Respondents' Rights at Key Research Stages – During Fieldwork

## J. Information to be Communicated at the Start of Fieldwork

5.1 The following information should be provided to respondents at the start of fieldwork, even though much of this information will have been communicated at recruitment:

- Details about the true nature and purposes of the study
- What will happen to the information they give
- Details of any viewing or recording
- Country-specific requirements for adverse event reporting

5.2 EphMRA does not recommend the use of sales representatives as market research interviewers.

## K. 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
- Respondents 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
- Respondents 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 respondents with regard to the performance of a product
- Encourage members of the public to ask a healthcare professional for a particular product.

**Sensitive Topics**

7.1 When a topic is considered sensitive, respondents 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 respondent 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, respondents should be interviewed by interviewers of the same sex, or given the choice to be so.

**Stimulus Material**

8.1 Stimulus material includes any material shown during the course of fieldwork e.g. product profiles, branding concepts, 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 respondents understand when they are providing feedback on draft materials, hypothetical scenarios, assumptions, a product in development or as yet unlicensed.

8.4 **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 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 BHBIA'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 products ('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 and Devices**

10.1 Companies should generally refer to their medical and regulatory departments for guidance on market research surveys that involve testing products and/or devices.

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 product license can only be taken by a respondent who is an existing user of the product and if a registered medical practitioner is present.
- If a product is licensed but the respondent 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. http://ec.europa.eu/health/files/eudralex/vol-1/dir_2005_28/dir_2005_28_en.pdf
  If the 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 In Mexico these are published by the regulator COFEPRIS at http://www.cofepris.gob.mx/AZ/Documents/Farmacovigilancia/Buenas%20pr%C3%A1cticas%20de%20Farmacovigilancia%20para%20las%20Am%C3%A9ricas.pdf

If subjects are taking non-prescription drugs (i.e. over the counter - OTC) products during market research surveys, it is recommended that an appropriate healthcare professional is present.

10.4 For market research involving medical devices only (i.e. there is no active product 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. http://ec.europa.eu/health/medical-devices/files/meddev/2_7_4_en.pdf

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/components 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, products and devices (active or placebo) 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.

## L. 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 would be possible to identify the individual.

**Consents Required**

11.2 Respondents 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.

11.3 At the start of fieldwork respondents MUST be informed if their personal data is to be passed on to the commissioning client company.

**Information to be Communicated to Respondents when Observed by Client**

11.4 If the agency is going to transfer recordings or live-stream non-anonymised fieldwork to the commissioning client company, respondents should be told:

- The name of the recipient company
  If respondents agree the company name can be withheld until the end of fieldwork to avoid bias or the threat of disguised promotion. However if respondents 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 respondents filmed in France that the film will be viewed in the USA.

When live observation takes place (i.e. there is no transfer of personal data to the commissioning client company) the client 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.

**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 respondents are not known and cannot become known to observers.

**In the UK** BHBIA guidance states that if fieldwork is viewed:

- Live via video-relay (including video-streaming) - The Data Protection Act 1998 requires that Client names are disclosed, so far as practicable, prior to viewing of non-anonymised fieldwork via video-relay. However, where revealing a client identity would bias or otherwise undermine the conduct of a research project, researchers may withhold the identity of the client at the outset of the research if withholding that information is unlikely to be detrimental to the participants. The client company name may be withheld until the end of the interview or, only where there is a genuine threat of disguised promotion by revealing the company name, indefinitely. When the client company name is withheld specific conditions MUST be met which are detailed in the full Guidelines.
- Delayed via video-relay (including video-streaming) - The Data Protection Act 1998 requires that Client names are disclosed, so far as practicable, prior to viewing of non-anonymised fieldwork via video-relay. However, where revealing a client identity would bias or otherwise undermine the conduct of a research project, researchers may withhold the identity of the client until the end of fieldwork if withholding that information is unlikely to be detrimental to the participants.

If there is a genuine threat of disguised promotion by revealing the company name and if withholding that information is unlikely to be detrimental to the participants, researchers may withhold the identity of the client indefinitely. If respondents refuse consent this MUST be respected.

**Passing on Recordings without Consent**

11.5 Recorded data (audio or video that could identify individual respondents) given to clients without respondent consent MUST be anonymised.

**When Written Consent is Required**

11.6 Respondents' written consent for audio or video recording should be obtained at the beginning of the interview before recording commences, oral consent is satisfactory **in Germany**. Where multiple purposes exist or are possible, explicit 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 Respondent Withdraws**

11.7 If a respondent withdraws from the research at any stage e.g. during a group discussion, their contribution MUST be withdrawn from the final analysis and reporting, if they request this.

**When Recipients of Recordings Change**

11.8 If the recipient(s) of the non-anonymised recorded data changes after respondents have given consent for its release, all respondents MUST be re-contacted (assuming consent for re-contact has been given) and consent given for further release, giving details of the people to whom the data will now be shown.

**Delayed Viewing of Fieldwork e.g. by video streaming**

11.9 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).

11.10 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. https://www.adm-ev.de/index.php?eID=tx_nawsecuredl&u=0&file=fileadmin/user_upload/PDFS/R01_E.pdf&t=1449297126&hash=a5dca29a0fc107a6eeabfe10935e729ba7ce273e

**Audio-only recordings**

11.11 If it is possible that the respondent could be identified by the audio-recording alone they should not be passed to client companies unless the respondent has given their informed consent, although requesting consent is prohibited by MR industry guidelines **in Germany**.

**Client Awareness of Restrictions on use of Recorded Data**

11.12 Clients should be made aware of the restrictions on the use of recorded data at the start of a project if there is a possibility that they may want to watch or listen to copies of recordings during or after the project.

**Protecting Data When it is Transferred**

11.13 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**

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

11.15 Observers should be informed of their responsibilities towards respondents and agree to:

- Withdraw from observing if a respondent is known to them/recognised to protect the respondent's anonymity. If an observer knows that they will subsequently have to deal with a respondent, the attendee MUST also withdraw. 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, however care should be taken to ensure that respondents are completely comfortable with this. **In Japan,** if a (HCP) respondent 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 respondents are known to observers should be ruled out before viewing.
- Respect the confidentiality of all information exchanged in interviews/groups.
  - Not record any respondent's personal data or record any information with the specific aim of establishing the identity of a respondent.
  - Not make any notes or recordings that could be attributed to a specific respondent.
  - Not use the information to influence future approaches to a respondent.
  - 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.

## M. 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 Respondents**

12.6 All respondents 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**

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| 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

| | EMA Guidelines | EphMRA Guidelines |
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| **Scope** | Suspected adverse reactions (serious and non-serious) and emerging safety issues associated with medicinal products for human use authorised in the EU.<br><br>A medicinal product is for:<br>– Treating or preventing disease in human beings<br>– Restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis<br><br>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)<br>All ARs suspected to be related to any of the active substances being part of a medicinal product authorised in the EU.<br><br>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.<br><br>Independent of the strengths, pharmaceutical forms, routes of administration, presentations, authorised indications, or trade names of the medicinal product.<br><br>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. | AER Guidelines apply to authorised medicines for human use.<br><br>AER applies to both prescription and non-prescription bound (over the counter) medicines.<br><br>AER requirements associated with medical devices should be agreed with the MAH.<br><br>AEs that relate to any product for which the drug company has need to be forwarded. Market researchers are not required to collect events cited for other companies' products.<br><br>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.<br><br>AEs should be forwarded whether cited in the company's brand or generic name.<br><br>AEs cited in groups of drugs should not be forwarded.<br><br>Companies should provide agencies with a list of products for which they hold the marketing authorisation. |
| **Definition of an Adverse Event** | 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.<br>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. | The definition of an adverse event is taken from the EMA's Guideline on good pharmacovigilance practices (GVP) Annex I – Definitions 2012.<br><br>Adverse event is an 'umbrella term' that includes adverse reactions and product complaints. |

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| **Definition of an Adverse Reaction** | 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.<br>Plus:<br>– Suspected or confirmed falsified product or quality defects<br>– Suspected transmission via a medicinal product of an infectious agent<br>– Misinformation in the product information<br>– Use of a medicinal product during pregnancy or breastfeeding<br>– Lack of therapeutic effect . . . unless the reporter has specifically stated that the outcome was due to disease progression<br>– For vaccines , cases of lack of therapeutic effect should be reported<br>– Drug interactions – drug/drug, drug/food, drug device and drug/alcohol<br><br>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. | An adverse reaction is directly linked to the medicine i.e. is caused by the medicine, the adverse event may not be.<br><br>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. |
| **Causality** | The definition of an AR implies at least a reasonable possibility of a causal relationship between a suspected medicinal product and an adverse event<br><br>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. | It is not the market researcher's responsibility to assign causality<br><br>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. |
| **Minimum Reporting Criteria** | 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. | For the purpose of reporting AEs, the minimum data elements for a case are:<br>1. Identifiable reporter<br>2. Identifiable patient or patients<br>3. Suspected adverse event<br>4. Suspected medicinal product.<br><br>Researchers should identify events |

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| | 1. Identifiable reporter<br>One or more identifiable reporter characterised by qualification (e.g. physician, pharmacist, other HCP, lawyer, consumer or other non-HCP) name, initials or address.<br><br>There are several types of primary sources [reporter]:<br>– 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.<br>– 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.<br><br>2. Identifiable patient<br>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.<br><br>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.<br><br>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)<br><br>3. Suspected medicine<br>One or more suspected substance/medicinal product<br><br>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<br><br>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.<br><br>4. Suspected adverse reaction<br>One or more suspected AR. | based on the information cited, they are not required to probe for missing reporting criteria.<br><br>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 a 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.<br><br>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. |

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| | 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.<br><br>Reports, for which the minimum information is incomplete, should nevertheless be recorded within the pharmacovigilance system for use in on-going safety evaluation activities<br><br>Reports should include the verbatim text as used by the primary source or an accurate translation of it | AEs should be reported even if the details are incomplete:<br>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<br>2. Patient – there should be a patient or a specific number of patients. Patient details should be collected if possible<br>3. Drug – there must always be a drug for which the company commissioning the MR is the MAH<br>4. Adverse Event – there must always be an AE of some type even if the detail is sparse<br><br>Describe the AE as clearly and carefully as possible, try to avoid paraphrasing |
| **Passing on Reporter Contact Details** | 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. | 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.<br>Contact details (i.e. personal data) cannot be passed on withoutconsent. 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.<br>In Germany MR industry guidelines prohibit revealing respondent identity 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. |

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| **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.<br><br>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<br><br>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:<br>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 |
| **Reporting Formats** | | There are two potential AER formats:<br>– AE Reporting Form - generally used when responses are generated or analysed on a respondent by respondent basis e.g. from one to one interviews or group discussions<br>– 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<br><br>The reporting format should be agreed |

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| | | with the MAH at the project start |
| **AE Reporting Form** | | The MAH should supply the AER form<br><br>EphMRA provide a standard AER form that can be used |
| **When and How To Complete AER Forms** | | Complete the AER form at the end of the interview – there is no need to interrupt the interview to fill it in<br><br>Collect as many details on the form as possible, ideally complete it with the help of the reporter<br><br>The company should provide an email or fax address to which completed AER forms should be sent |
| **The Format of AE Tabulations** | | AER tabulations should show:<br>– Number of respondents citing event<br>– Question base i.e. how many respondents answered the question<br><br>The format should be agreed with the MAH in advance of data processing |
| **Quality Management and Training** | 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.<br><br>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 in accordance with internal policies and procedures.<br><br>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. | 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.<br><br>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 |

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| **Confirmation and/or Reconciliation Process** | 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. | 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<br><br>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<br><br>Reconciliation form should include:<br>– Number of AEs identified (not just reported)<br>– Summary by each AE of respondent ID, product (s) and event details |
| **Syndicated Studies** | 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<br><br>* "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. | 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<br><br>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<br><br>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 agency should forward AEs generated by these questions |

| | | |
|---|---|---|
| **Longitudinal Patient Databases** | | Longitudinal patient databases e.g. GPRD (General Practice Research Database) are out of scope<br><br>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) |
| **If You Have Questions** | | The MAH's PV department is a most important source of guidance on requirements for forwarding AEs |

| EphMRA Adverse Event Reporting Form – TEMPLATE | | | |
|---|---|---|---|
| **MR Agency Information** | | | |
| Agency name | | | |
| Telephone number | | | |
| Researchers name | | | |
| Date aware of Adverse Event | | | |
| Project title/reference number | | | |
| Respondent 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 |
| **Respondent/Reporter details** | | | |
| Reporter/respondent name | | | |
| Reporter type (E.g. doctor, patient) | | | |
| Respondent's address/contact information if willing to provide | | | |
| | NOT WILLING TO PROVIDE | | |
| Willing to be contacted for follow up | YES | NO | |
| | SIGNATURE | | |
| Doctor's name & address if patient is a respondent/reporter | | | |

# 6. Respondents' Rights at Key Research Stages – After Fieldwork

## N. Combining Research Data

13.1 Combining data is permissible as long as personal data is not released to the client company when data is combined.

## O. Storage and Security

**Consent for Storage of Personal Data for Future Use**

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

**Storage Duration**

13.3 Personal data MUST be destroyed as soon as the purpose of the study 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.

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

**Security**

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

13.6 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

## P. Reporting Market Research

13.7 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.

## Q. Publishing Market Research

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

13.9 **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.

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

13.11 Full details of the source should be referenced.

13.12 **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.casro.org/?page=TheCASROCode
**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.

13.13 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. Respondents' Rights by Research Approach

## R. Face to Face Methodology

14.1 The name of the agency for which the interviewer is working (whether employed or sub-contracted) should be given verbally and it is good practice for the interviewer to give his/her name to the respondent.

## S. 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 To gain the trust of respondents without having the benefit of face-to-face contact, the interviewer should 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 respondents via mobile phones (whether by voice, text or email), with regard to respondent 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 respondent 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 respondents and provides a '*Summary of regulations covering unsolicited contacts (business to consumer)*' May 2013, this is available on the ESOMAR website.

**Respondent Costs**

15.5 If using a mobile phone means the respondent incurs a cost this should be reimbursed, researchers should ensure that participating in market research does not disadvantage respondents financially.

**Use of Apps**

15.6 Respondent consent is required for the use of an app and respondents 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**

15.7 **In Germany and the UK** the use of predictive/auto-diallers is restricted. **In the USA** they are permitted only if the respondent 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. https://www.adm-ev.de/index.php?eID=tx_nawsecuredl&u=0&file=fileadmin/user_upload/PDFS/R04_E_08.pdf&t=1448018843&hash=117a80f27e7e7203045054a5fd75eb0e86285d6c

**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 organizations 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 reserach calls made to mobiile phones using an auto-dialler only with the “prior express consent“ of the intented 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).

## T. 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 respondents 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 respondents 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 respondents of the extended nature of ethnographic research at the point of recruitment before they agree to participate. Timings should be clear.
- Inform respondents 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

## U. Online & Mobile Devices

**Definitions**

17.1 Online or internet research refers to research in which a respondent 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 a social networking site
- Any other collection of personal data in the online environment for the purpose of market research

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 respondents 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 www.esomar.org/index.php/26-questions.html. These cover panel recruitment, project management, monitoring, maintenance and data protection issues.

17.3 A respondent'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 Informed consent and a means to provide it are required. Written consent is preferable but use of an on-screen check box is generally acceptable for data protection purposes.

17.6 Respondent consent is required for the installation and use of software such as an app and respondents 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. The statement should be easy to find, easy to use and comprehensible, including by children when appropriate. It must include information such as what personal data is collected, how it is used, how it will be managed and the conditions under which it will be shared, as well as how to get more information or make a compliant.

A guide to privacy policies, their standard elements and an example privacy policy is provided within ESOMAR's Guideline for Online Research Aug 2011.

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 respondents fail to complete the exercise for any reason their rights are protected.

17.9 If a repeat or follow-up survey is intended, a statement concerning Data Protection MUST be displayed on the respondents' screen by the end of the first interview (although this is not compulsory **in Spain**), while obtaining their consent for the necessary storage of their address data. Respondents should also be given the opportunity to print out this statement. The respondents 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, respondents' email addresses MUST be kept confidential, so for instance blind copying should be used.

**Respondent Costs**

17.11 Respondents should be alerted to any costs they may incur e.g. online charges and recompensed for these.

**Researcher or Agency Contact Details**

17.12 Respondents 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**

17.13 Researchers MUST use adequate technologies to protect personal and sensitive data when collected, transmitted or stored on websites or servers.

17.14 Clients should be made aware of the potential risks of using confidential information in online or mobile surveys (e.g. within product profiles). 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**

17.15 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 explicit consent may be required (depending upon national legislation.). ESOMAR provides a Practical Guide on Cookies

**Interview Duration**

17.16 Respondents 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**

17.17 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**

17.18 Researchers should avoid intruding unnecessarily on the privacy of respondents. ESOMAR advises that unsolicited e-mail approaches to potential respondents 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 therefor 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 organizations 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**

17.19 Studies should provide either the client's identity or an opportunity to ask for it if there is no interviewer to make the request of spaontaneously, at an appropriate point within the study - the client's identity should be given if sampling from a customer database (i.e. the client supplied a list of potential respondents).

**Active Self-Selection of Respondents in Germany**

17.20 **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*

17.21 Measures should be in place to validate the identity of respondents (to avoid surrogate respondents) 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%20AMSRS%20CASRO%20MRS%20Mobile%20Research%20Guidelines.pdf

17.22 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 organization;
- Install or utilize 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**

17.23 Respondents 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.

Explicit 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.
http://www.esomar.org/knowledge-and-standards/codes-and-guidelines/guideline-for-online-research.php

**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**

17.24 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 respondents 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.

17.25 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.*

17.26 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

## V. 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)."

**Website Terms and Conditions**

18.2 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 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 personally identifiable information (PII) can only be provided to the client if 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**, respondent identity must remain anonymous and respondents 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 and 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 respondent/contributor consent to pass their personal data to the client company.

**<u>Active market research</u> 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.

18.11 Contributors should be provided with contact information for the researcher or research agency.

18.12 Researchers should publish a privacy policy 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.

**<u>Adverse Event Reporting</u>**

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 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. Respondents' Rights by Respondent Type

## W. 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 respondents 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.

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 may be prohibited, even if the data is anonymised. 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 collected from HCPs and referring to patients must be cumulative. No personal patient data must be collected during market research, since this is regarded as a non-interventional/pharmaco-epidemiological study, governed by the rules described in article 26 of the present Chapter of the Code."

## X. 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.

http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf

## Z. Vulnerable Respondents

**Definition**

20.1 Vulnerable respondents 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 respondents because of their age, physical or mental health. A vulnerable respondent 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 respondents 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 respondent 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 respondent 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, generally speaking a 'child' is a minor 14 years old or less and a 'young person' is 15 to 17 years of age. **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.

**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 respondents 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) should 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 respondents 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 any products that are 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.

**Incentives**

21.17 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 or Device Testing**

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

21.19 If children/young people are to be asked to take part in any form of product or device testing, researchers should take special care to ensure that the products/devices 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**

21.20 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 respondents 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 respondent 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 respondent'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.

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

**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 respondent 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 respondent to collect information for market research purposes.

**Interviewer** – The person who collects data from respondents 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).

**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 respondents. Primary data is derived from new and original research designed to address a specific purpose.

**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, respondent 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 respondent and the research results

**Recruiter** – The person who identifies and invites respondents 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.

**Respondent –** 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.

**Secondary market research –** Involves **c**ollecting 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 respondent; 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 respondent 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.

For more terms and definitions see EphMRA's Lexicon - A pocket guide to pharmaceutical marketing and market research terms and definitions at www.ephmra.org

## Sources

**Legislation Supporting The Code of Conduct**

- EU Data Protection Directive 1995
- EU Directive 2001/83/EC on the Community Code relating to Medicinal Products for Human Use
- EU Regulation 726/2004 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
- EU Council Directive 93/42/EEC concerning medical devices
- EU Directive on Privacy and Electronic Communications (2002/58/EC) 2003
- Health Insurance Portability and Accountability Act (HIPAA)

**France**

- ASOCS Charte De Pratiques Loyales En Matière D'Etudes Des Opinions Et Comportements Dans Le Domaine De La Sante
- ASOCS, INFOSTAT & UDA Le Guide Des Relations Entre Laboratoires Et Societes D'Etudes

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- Arbeitskreis Deutscher Markt- und Sozialforschungsinstitute e. V. (ADM), Declaration of the Federal Republic of Germany concerning the ICC/ESOMAR International Code of Market and Social Research 2008
- ADM, Guideline for Studies in Public Health Service for Purposes of Market and Social Research Apr 2013
- ADM, Guideline Concerning Recording and Observation of Group Discussions and Qualitative Interviews 2006
- ADM, Standards for Online Surveys 2007
- ADM, Guideline on the Interviewing Minors Jul 2006
- ADM Guideline on Telephone Surveys Jan 2008
- ADM, Guideline on the Treatment of Addresses in Market and Social Research May 2011
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- Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V. (FSA) FSA Code of Conduct on the Collaboration with Healthcare Professionals 2015

**Italy**

- ASSIRM, Code of Professional Ethics
- ASSIRM, Code of ethics and conduct for the processing of personal data for scientific and statistical purposes
- Farmindustria, Code of Professional Conduct July 2014

**Mexico**

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

**Netherlands**

- Code of Conduct for Pharmaceutical Advertising July 2015
- MOA Code of Conduct for research and statistics (Gedragscode voor onderzoek en statistiek)
- Wet bescherming persoonsgegevens
- Telecommunicatie wet

- CGR Richtlijnen niet-WMO plichtig onderzoek
- Gedragscode Geneesmiddelenreclame
- CGR Uitwerking Normen Gunstbetoon
- Toelichting gedragsregels openbaarmaking financiële relaties,
- MOA guideline Publiceren over marktonderzoek
- MOA Onderzoekfilter www.onderzoekfilter.nl

**Scandinavia**

**Denmark**

- The Danish Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals 2014

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- Pharma Industry Finland (PIF), Code of Ethics, 2014
- Market Research Association SMTL, Code of Ethics, 2011
- Market Research Association SMTL, Tietosuojakäytänne (Privacy Policy) 2003

**Norway**

- Legemiddelindustriforeningen (LMI) – the Norwegian Association of Pharmaceutical Manufacturers Rules For Marketing Of Medicinal Products 2014

**Sweden**

- De forskande läkemedelsföretagen (LIF), Ethical rules for the pharmaceutical industry in Sweden, 2015
- Svenska Marknadsundersökningsföretag (SMIF), Children and Youth Policy, Jan 2013
- Svenska Marknadsundersökningsföretag (SMIF), Tillämpningsregler PUL, Privacy Application Rules , 2010

**Spain**

- AEDEMO, Proteccion de Datos e Investigacion de Mercados 2007 Privacy & Market Research
- Farmaindustria, Code of Good Practice for the Promotion of Medicines and Interrelation of the Pharmaceutical Industry with Healthcare Professionals 2014

**Turkey**

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**UK**

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- Association for Qualitative Research (AQR), Qualitative Research Recruitment 2002
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- MRS Guidelines on the Privacy and Electronic Communications Regulations May 2011
- MRS Guidelines for Online Research Sep 2014
- Guide to Observers' Legal & Ethical Responsibilities
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- MRS Online data Collection and Privacy Response to Submissions Apr 2012
- MRS Qualitative Research Guidelines including Observational and Ethnographic and deliberative Research Sep 2014
- MRS Questionnaire Design Guidelines Sep 2014
- MRS Use of Predictive Diallers Jan 2011
- MRS Using Research Techniques for Non-Research Purposes Nov 2010
- Office of Information Commissioner (ICO), Guide to Data Protection

**Europe**

- European Federation of Pharmaceutical Industries and Associations (EFPIA) Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals 2014
- EFPIA Code On Disclosure Of Transfers Of Value From Pharmaceutical Companies To Healthcare Professionals And Healthcare Organisations 2014
- European Society for Opinion and Marketing Research (ESOMAR), Online Research Guideline, 2015
- ESOMAR Guideline for Conducting Mobile Market Research Oct 2012
- ESOMAR Guideline on Social Media Research Jun 2011
- ESOMAR Guidelines on the Mutual Rights and Responsibilities of Researchers and Clients Oct 2010
- ESOMAR How to Commission Research 2001
- ESOMAR International Code of Marketing and Social Research Practice 2007
- ESOMAR Interviewing Children and Young People 2009
- ESOMAR Distinguishing Market Research from Other Data Collection Activities Mar 2009
- ESOMAR Passive Data Collection, Observation and Recording Feb 2009

**Korea**

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

**USA**

- Council of American Survey Research Organisations (CASRO) Code of Standards and Ethics for Survey Research
- Children's Online Privacy Protection Act (COPPA) 1998
- Health Insurance Portability and Accountability Act (HIPAA) 1996
- Marketing Research Association (MRA), Code of Marketing Research Standards 2013
- Pharmaceutical Research and Manufacturers of America (PhRMA), Code on Interactions with Healthcare Professionals Jan 2009

## Appendices

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

Pro Forma 1 – Recruitment Agreement

| **Recruitment Agreement** | |
|---|---|
| Project Title: | Project No: |
| **Nature of Project** | |
| Subject and purpose of market research study: | |
| Methodology and Approach | |
| **Fieldwork** | |
| Location: (If online or telephone, please state this) | Duration: |
| Date: | Start Time: |
| **Incentive** | |
| Type: (e.g. cash) | Amount: |
| **Respondent Signature** | |
| Signature: | Name (please print) |
| **Respondent 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:<br>(e.g. cash) | Incentive Amount: |
| **Declaration** | |
| I confirm that the information I have given during the course of this interview/group discussion represents my views on the subject matter.<br><br>I confirm that I have received the incentive detailed above in appreciation for my contribution to the project. | |
| **Respondent Signature** | |
| Signature: | Name (please print) |
| **Respondent Code Number** | |
| Code Number | |

**Respondent Consent Allowing Client Access to Recordings of Market Research Fieldwork**

| **Project Details** | |
|---|---|
| Project Title: | Project No: |
| Agency: | Location of Fieldwork: |
| Date of Fieldwork: | Start Time of Fieldwork: |

**Declaration**

I understand that the company that commissioned this market research study

_____

(company name, may or may not be specified)
will have access to recordings of this market research interview/group discussion.

I understand that the purpose(s) of the company having access is:

_____

_____

_____

_____

The people in the company who will listen to or view the recordings will be in the following functions/roles:

_____

_____

_____

I understand that all those listening 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.

| **Signatures** | |
|---|---|
| Respondent Signature: | Name (please print) |
| Agency Signature: | Name (please print) |

| **Respondent 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**

On behalf of the commissioning client company I can confirm that the recording(s) of market research fieldwork from the above study will only be used for the following purpose(s):

_____

_____

The only people in the company who will listen to or view the recordings will be in the following functions/roles:

_____

_____

And the recording(s) will be in the secure care of: _____

On behalf of the commissioning client company I can confirm that:

- Those listening to or viewing the recording will respect the confidentiality of all information exchanged in market research interviews/groups
- No sales approaches will ever be made to respondents 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**

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

EphMRA

European Pharmaceutical Market Research Association

# CODE *of* CONDUCT *2016*