

**EphMRA**

*European Pharmaceutical Market Research Association*

CODE *of* CONDUCT *2011*

# EphMRA CODE *of* CONDUCT 2011

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## A. Introduction

### 1 Purpose

- 1.1 The Code of Conduct is designed to provide comprehensive and up-to-date ethical and legal guidance to support EphMRA members when they carry out multi-country, primary healthcare market research. Primary healthcare market research 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.

### 2 Scope

#### Geographic Scope

- 2.1 The Code provides pan-European guidelines, although its development has focused upon the major European markets of France, Germany, Italy, Spain and the UK, plus the USA and the Scandinavian territories of Denmark, Finland, Norway and Sweden. It offers international guidelines rather than country specific detail however key inter-country differences are highlighted where they exist.

#### Members' Responsibilities

- 2.2 EphMRA strongly recommends that all members adhere to the Code of Conduct and ensure that all personnel employed or sub-contracted on their primary market research studies understand and agree to abide by the Code. It is also recommended 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 of Conduct.

#### Relationship with Other Codes and Legislation

- 2.3 EphMRA's Code of Conduct complements other professional codes of conduct/practice e.g. ICC/ESOMAR's International Code of Marketing and Social Research, CASRO's Code of Standards and Ethics for Survey Research, the EFPIA Code on the Promotion of Prescription-Only Medicine to, and Interaction with, Healthcare Professionals etc. It is not intended to replace the need to reference these codes/guidelines and where appropriate readers are referred to complementary/additional sources of information.

It should also be remembered that local codes must also be observed. For example **in the UK** BHBIA member companies must adhere to the BHBIA's Legal & Ethical Guidelines.

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

### Principles of the Guidelines

- 2.5 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 are paramount, 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. Undertakings made to respondents must be honoured.
  - V. Data collection must be adequate, relevant and not excessive.
  - VI. 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.
  - VII. Data must be processed fairly and lawfully, and only used for the specific and lawful purposes for which it was obtained.
  - VIII. There must be no unauthorised or unlawful processing, loss, destruction or damage to personal data.
  - IX. Data can only be transferred 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 Sources

- 3.1 The Code of Conduct is based upon key legislation:
- EU Data Protection Directive 1995
  - US Safe Harbor Framework approved by the EU in 2000
  - 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
- 3.2 The Code also draws heavily upon the following codes of practice:
- BHBIA Legal & Ethical Guidelines 2009
  - CASRO (Council of American Survey Research Organisations), Code of Standards and Ethics for Survey Research
  - Health Insurance Portability and Accountability Act (HIPAA)
  - ICC/ESOMAR International Code of Marketing and Social Research Practice 2008.
  - Market Research Society's Code of Conduct 2010
  - Marketing Research Association (MRA), Code of Marketing Research Standards 2007
- 3.3 EphMRA is grateful to EFPIA, CASRO and the BHBIA for their generous help and support in preparing this Code.

## B. Key Definitions

### 4 Market Research

- 4.1 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*
- 4.2 Market research is not a commercial communication or a selling opportunity.
- 4.3 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.
- 4.4 EphMRA's Code of Conduct uses the following terms as defined by ESOMAR:
- **Researcher** – an individual or organisation carrying out, or acting as a consultant on, a market research project, including those working in client organisations.
  - **Client** – any individual or organisation that requests, commissions or subscribes to all or part of a market research project.
  - **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.
  - **Interview** – any form of contact with a respondent to collect information for market research purposes.
- www.esomar.org/uploads/pdf/professional-standards/ICESOMAR\_Code\_English\_.pdf Aug 2009*
- 4.5 Market research that meets the definition above, 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**).

### 5 Research and Non-Research Purposes

- 5.1 A non-research purpose is when data are collected for reasons other than to enhance understanding for any other purpose than that described above (see 4.1).
- 5.2 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*

- 5.3 Consequently direct action must not be taken in relation to named individuals or organisations as a result of market research.
- 5.4 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.
- 5.5 Database building is a non-research purpose. Although market research and database building use similar techniques on occasion they are fundamentally different activities. Database building requires individual information which cannot because of the nature of the activity be treated confidentially. Market research databases may only be used for the purposes of generating a sample. 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.
- 5.6 When researchers are fulfilling their role as researchers they must not conduct other non-research activities without the prior informed consent of respondents.
- 5.7 Non-interventional research involves the collection of scientifically valuable information for the purpose of answering clinical questions for medicinal products which have a marketing authorisation. Non-interventional research should not be confused with market research. The term 'non-interventional' means that the healthcare provider's decisions regarding the proper treatment and care of the patient are made in the course of normal clinical practice. 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*.

## 6. Data Protection and Privacy

- 6.1 The 1995 EU Data Protection Directive and the US's Safe Harbor Principles cover the collection of data relating to an identifiable person. This data is referred to as 'personal' data, although in Germany it may be described as an 'address' and in Spain as 'private individual records'. Personal data includes postal codes, cell phone numbers and email addresses as well as full names and postal addresses.

An IP address is necessary to link a PC/laptop to the internet and is generally recorded by websites and servers (users tend to be unable to prevent this). 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). Consequently 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 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.

If a private company or organisation hold personal data it is covered by the Data Protection Directive if it either is held on a computer or is held on a 'relevant filing system'. A relevant filing system is one which is structured by reference to individuals, or by reference to criteria relating to those individuals, in a way which allows information relating to specific individuals to be readily accessible.

- 6.2 The guiding principles of the Data Protection legislation/Safe Harbor Principles are:
- **Transparency** – ensuring individuals have a very clear and unambiguous understanding of the purpose(s) for collecting the data and how it will be used;
  - **Consent** – at the time that the data is collected, individuals must give their consent to their data being collected, and also at this time, have the opportunity to opt out of any subsequent uses of the data.

[www.mrs.org.uk/standards/downloads/revise/legal/A\\_BasicGuidetoTheDataProtectionAct1998.pdf](http://www.mrs.org.uk/standards/downloads/revise/legal/A_BasicGuidetoTheDataProtectionAct1998.pdf) Aug 2009

- 6.3 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 or the Safe Harbor Principles 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.

- 6.4 In addition, **in the USA**, that part of the Health Insurance Portability and Accountability Act (HIPAA) known as the HIPAA Privacy Rule, is a federal law which gives the individual rights over their health information (i.e. health status, provision of health care or payment of healthcare that can be linked to an individual) and sets limits upon who may access this information. A HIPAA-defined covered entity cannot use or share with any person or entity other than a "Business Associate" the health information of individuals without their written permission for non-health care purposes, although there are specific exceptions to this prohibition. There is no restriction upon the use of protected health information if it has been de-identified in accordance with the standards set by the Privacy Rule (see 19.3).

- 6.5 Personal data covered by the Data Protection Directive includes data recorded manually, electronically, or digitally.

- 6.6 Once all identifiers linking data to a respondent have been removed then it no longer constitutes personal data and is not covered by the Data Protection Directive/Safe Harbor Principles. It is permissible to use a unique identifier (e.g. a serial number) to identify a respondent but the file linking personal data to the unique identifier must be stored entirely separately from the anonymised respondent data.

- 6.7 Personal data is protected by the provisions of the Data Protection Directive/Safe Harbor Principles even when taken out of the country where the respondent lives.
- 6.8 The transfer of personal data to non-EU/ 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:

**Model Clauses** – The European Commission has published model contractual clauses. These are designed to facilitate the safe transfer of personal data from the European Economic Area (EEA) to all third countries, protecting the privacy of individuals. The European Commission has produced two sets of model clauses. One covers controller-to-controller transfers and the other controller-to-processor transfers. The clauses commit all parties to complying with the data protection standards required by the Data Protection Directive.

**Binding Corporate Rules (BCR)** – These are a mechanism for transferring personal data (outside the EEA) throughout a single multi-national organisation. BCR have to be approved by each European data protection authority involved but the approval process is simplified - an application is made to one national 'lead' data protection authority in Europe and that authority then liaises with the other authorities to seek approval.

For further information on Model Clauses or Binding Corporate Rules see:

[http://www.ico.gov.uk/upload/documents/library/data\\_protection/detailed\\_specialist\\_guides/international\\_transfers\\_legal\\_guidance\\_v3.0\\_171208.pdf](http://www.ico.gov.uk/upload/documents/library/data_protection/detailed_specialist_guides/international_transfers_legal_guidance_v3.0_171208.pdf)

**The Safe Harbor Framework** – In order to ensure adequate privacy protection, the US Department of Commerce, in consultation with the European Commission developed the 'Safe Harbor Framework'. US based organisations can guarantee adequate data privacy protection through voluntary participation in the Safe Harbor Program. Organisations that decide to participate must comply with its requirements and publicly declare that they do so.

Further information is available at:

[ec.europa.eu/justice\\_home/fsj/privacy/modelcontracts/index\\_en.htm](http://ec.europa.eu/justice_home/fsj/privacy/modelcontracts/index_en.htm)

[www.export.gov/safeharbor/eg\\_main\\_018236.asp](http://www.export.gov/safeharbor/eg_main_018236.asp) Aug 2009

- 6.9 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 and US companies that participate in the US-EU Safe Harbour Framework.

## C. Respondents' Rights

### 7 Fundamental Rights

- 7.1 All respondents must be treated fairly and reasonably, with care and courtesy.
- 7.2 All market research must comply with local government legislation.
- 7.3 Respondents' legal and ethical rights are paramount and take precedence over the needs of the market research project – without exception.
- 7.4 Respondents' physical and emotional well-being is paramount and should always be protected. Researchers must take all reasonable precautions to ensure that respondents are in no way directly harmed or adversely affected as a result of participating in a market research project.

### 8 Informed Consent

- 8.1 *“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.”*

*[www.esomar.org/uploads/pdf/professional-standards/ICCESOMAR\\_Code\\_English\\_.pdf](http://www.esomar.org/uploads/pdf/professional-standards/ICCESOMAR_Code_English_.pdf) Aug 2009*

The rights of specific respondent types such as the vulnerable, children, are detailed within Section F.

- 8.2 Information detailing an individual's physical or mental health is classified as 'sensitive personal data' under the Data Protection Directive/HIPAA Privacy Rule and requires explicit consent for its use (see 19.3).
- 8.3 Specific consent is not required for the use of anonymised and non-attributable responses.
- 8.4 Informed consent guarantees respondents the right not to participate and the right to withdraw from the interview at any time.

### 9 Confidentiality & Anonymity

- 9.1 It must be made clear to respondents that all personal data collected during a research project will be treated confidentially and are purely for the purposes of market research.
- 9.2 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.

- 9.3 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 permission. Passing any respondent data to the client is always forbidden **in Germany**.
- 9.4 The respondent's right to confidentiality can be waived – except **in Germany** – 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 the USA**, the HIPAA Privacy Rule requires that the patient sign an authorisation for the disclosure of protected health information to any third party other than a “Business Associate” of the “Covered Entity” that is very specific and includes the ability of the patient to revoke consent.
- 9.5 **In Germany** federal data protection legislation requires personal data to 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*  
[www.adm-ev.de/pdf/Kernprobleme\\_E.pdf](http://www.adm-ev.de/pdf/Kernprobleme_E.pdf) Aug 2009
- 9.6 Physicians have a duty of confidentiality towards their patients. Information about a patient may be obtained for market research from patient records without patient consent 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](http://www.hhs.gov/ocr/privacy/index.html) Aug 2009) or if the patient has given explicit written consent.

## 10 Disguised Promotion and Competitive Intelligence

- 10.1 Market research must not be used as a means to influence the attitudes or behaviour of respondents. It must not be used for the direct purposes of promotion or selling, generally referred to as ‘selling under the guise of’ or ‘disguised promotion’.
- 10.2 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.

## D. Respondents' Rights at Key Research Stages

### 11 Before Fieldwork

#### Proposals

- 11.1 **In Spain**, pharmaceutical 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.

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](http://www.farmaindustria.es/Farma_Public_ING/Codigo/codeofsanitaryprofessionals/index.htm)

**In Spain** market research studies must be approved prior to being carried out by the pharmaceutical company scientific service or by the compliance officer, this is required by the Spanish Code of Good Practices for the Promotion of Medicines and Interaction with Healthcare Professionals Oct 2010.

- 11.2 **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 studies to be conducted with healthcare professionals in Sweden. The LIF guidelines also apply for Skålland in Denmark

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. The database can be found at the following web address - <http://www.lif.se/cs/default.asp?id=59886&ptid>

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.

- 11.3 Clients must be informed if any part of the study is to be sub-contracted outside of the agency. If requested the identity of the sub-contractor must 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.

#### Recruitment

- 11.4 The size of the sample must be appropriate to meet the market research objectives. If the sample size is unnecessarily large, the market research may be considered a promotional vehicle.
- 11.5 Researchers have a responsibility to provide samples representative of the target group. If convenience sampling (i.e. when the respondents that are most conveniently available are selected as part of the sample) is the basis for sample selection, it is good practise to monitor the frequency with which potential respondents participate in market research and try to avoid over-researching individuals.
- 11.6 When studies are conducted that draw respondents from a list supplied by an agency, recruiter or the client company, the list provider must ensure that the list conforms to local data protection and privacy legislation.

Lists that are drawn from sources within the public domain do not generally require the permission 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 party and that party is contractually designated the 'data processor' (the list holder being the data controller), then again, the permission of the individual need not be sought. Similarly if a list of detailed physicians was passed to a market research agency to allow them to draw a sample from it, as long as the agency had been contractually designated the data processor (the client company being the data controller) this does not constitute the 'transfer' of personal data and does not require the permission of the listed individuals.

If however local law/regulations demand that the explicit permission 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 permission for their personal data to be held and told why their personal data is being held

The client company must not be informed of the identity of market research participants, i.e. who on the list was interviewed.

- 11.7 When lists of named individuals are used for sample selection the source of the list must be revealed to potential respondent(s) at an appropriate point in the interview, if requested. **In Finland**, a researcher must not disclose the identity of the sponsor (unless legally required to do so) to any third party without the permission of the sponsor.
- 11.8 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'
- Agreed to be re-contacted for further research

*www.mrs.org.uk/standards/downloads/Using\_research\_techniques\_for\_non\_research\_purposes.pdf Aug 2009*

#### 11.9 Respondents must:

- Be informed about the research study in a consistent, clear and unambiguous manner
- Not be misled into agreeing to participate and must be told:
  - The type of organisation sponsoring the market research e.g. a pharmaceutical company
  - The subject and the purpose of the market research
  - If there is to be observation and/or recording, what sort and types of observers
  - The name of the researcher or research agency who will be conducting the discussion
  - The length of the interview
- Be told of their rights – confidentiality, anonymity, that they can withdraw at any time
- Be given contact details – identity of agency, researcher's name (if appropriate) and a contact name and telephone number
- Be told what will happen to their data (including personal data) and how it will be used
- Healthcare professionals must be informed of the need to report adverse events uncovered during the study (See 13.34). Templates for a standard text are available in Germany (<http://www.akdae.de/en/20/905UAWBerichtsbogen.pdf>) and the UK (<http://www.bhbia.org.uk/Portals/2/Files/ad%20event%20form%20example.doc> [www.bhbia.org.uk](http://www.bhbia.org.uk)). 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 the USA** the Marketing Research Association provides a 'Respondent Bill of Rights' which details respondents' rights when interviewed see page 37.

*www.mra-net.org/rq/practices.cfm?ID=bill Aug 2009*

11.10 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.

11.11 **In Germany, Italy Norway and Sweden**, the ADM, 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 on Interviewing Physicians for Market and Social Research Purposes [www.adm-ev.de/richtlinien](http://www.adm-ev.de/richtlinien) Aug 2009*  
*ASSIRM, Directive on the interviews with medical staff for purposes of market research and social*

**In Norway** it is understood that drug brand or generic names cannot be used within market research unless approval for the study from the Norwegian health authorities has been given.

11.12 Data collected at recruitment must not be used for any purpose other than the purpose for which permission was granted. Seeking permission for other uses retrospectively is not allowed.

11.13 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. This advice rests

on the assumption that the physician's status as an opinion leader does not constitute a piece of identifiable personal data and so would not contravene Data Protection legislation.

#### Recruitment Using Client Databases

- 11.14 The use of client databases as a basis for drawing a sample is allowed as long as local regulations have been adhered to as detailed in 11.4. **In Germany** federal data protection legislation requires that respondents are 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.
- 11.15 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.
- The respondent has the right to request the deletion of any or all of their personal data from the database at any time.
- 11.16 Client databases must be returned to the client or destroyed at the end of the project.

#### Physician Recruitment of Patients

- 11.17 Physicians may act as intermediaries to recruit patients by inviting patients to take part or passing on questionnaires on behalf of the agency, they must however:
- Ensure that patients understand that their participation is voluntary
  - Not disclose the patient's identity to the agency until the patient has agreed to participate.
- 11.18 If the patients reply directly to the agency, the doctor must not be told which patients are to/have participated.

If vulnerable patients or children are to be recruited via the physician additional guidelines apply – see 20 and 21.

#### Recruitment Agreements

- 11.19 All members must document an agreement between agency or 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 do not require a written agreement in advance of fieldwork. 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*.  
[www.efpia.eu/content/default.asp?PageID=559&DocID=3483](http://www.efpia.eu/content/default.asp?PageID=559&DocID=3483)

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 (assuming they contain personal data) must be destroyed when the purpose of the market research study is redundant.

**In the UK** the BHBI states that to conform to Clause 20 of the ABPI's Code of Practise 2008, 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 BHBI Guidelines.

[www.bhbia.org.uk/Library/EthicalandLegalFrameworkBHBIAGuidelines/tabid/143/Default.aspx](http://www.bhbia.org.uk/Library/EthicalandLegalFrameworkBHBIAGuidelines/tabid/143/Default.aspx) Aug 2009

[www.abpi.org.uk/Details.asp?ProductID=333](http://www.abpi.org.uk/Details.asp?ProductID=333) Aug 2009

### Re-contacting Respondents

- 11.20 Informed consent requires that if it is necessary to contact a respondent again to ask further questions (other than for quality control purposes), permission for re-contact must be sought at the time of the recruitment interview or during the interview; even if only simple clarification is needed.
- 11.21 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.
- 11.22 **In Germany**, if personal data is stored for re-contact for which explicit 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. *ADM Guideline on the Treatment of Addresses in Market and Social Research* [www.adm-ev.de/richtlinien](http://www.adm-ev.de/richtlinien) Aug 2009

### Incentives

- 11.23 An ‘incentive’ is any benefit given to a respondents 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 normal hourly fee charged by that person for their professional consultancy or advice
  - Appropriate to the respondent type
  - Appropriate to the task(s).
  - For patients/members of the public the incentive is a token of appreciation – not a fee for time.
  - Handled only by the agency.
- 11.24 Internal company guidelines should be observed if they exist.
- 11.25 Panel members should be made aware of the approximate level of commitment and/or length of time required before the incentive will be paid.

- 11.26 **In Spain**, payment of incentives must be in cash (cheques and bankers drafts are acceptable). Exceptionally, and with the prior authorisation of the USD some payments in kind may be made.
- 11.27 **In the UK** pharmaceutical companies must make publicly available details of payments made to healthcare professionals in relation to market research – unless the company is *not* aware of the identities of those participating in the market research. See ABPI Code of Practice for the Pharmaceutical Industry 2011, clause 20.2 – 20.3, for further details.
- 11.28 **In Sweden** if remuneration for healthcare professionals exceeds SEK 1000, LIF guidelines state that the study will no longer be considered market research in which case healthcare professionals require the approval of their superior(s) to participate.
- 11.29 **In the USA** the federal Sunshine Act signed into law in late March does not include mandatory reporting of survey incentives made by drugs companies or their agents to doctors. The Bill excludes thank you payments for taking part in surveys provided the company sponsoring the research is unaware of the respondents' identity. The position of the states of California, Columbia, Maine, Massachusetts, Minnesota, Vermont and West Virginia is detailed within the appendices on page 38 - US State Law Summaries.
- 11.30 Incentives are not allowed in the following situations:
- That could influence opinion or behaviour e.g. to encourage prescription of a drug; excessive payments that could be seen as an attempt to buy good opinion or reward buying behaviour
  - 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 details.
- 11.31 With regard to free prize draws, respondents must not be required to do anything (including but not limited to participating in a market research exercise or returning a questionnaire) to be eligible for entry to a free prize draw. 'Free' includes any method of communication (post, telephone or other) at a standard rate.
- 11.32 The personal details of respondents eligible for incentives are confidential, so cannot be passed to clients without permission, this permission must not be linked to receipt of an incentive.
- 11.33 **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. 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.
- ADM Guideline on the Interviewing Physicians for Market and Social Research Purposes* [www.adm-ev.de/richtlinien](http://www.adm-ev.de/richtlinien) Aug 2009
- ASSIRM Directive on the interviews with medical staff for purposes of market research and social* [www.assirm.it/index.php?ml=Codici-e-Regole&11=Direttiva-Farma](http://www.assirm.it/index.php?ml=Codici-e-Regole&11=Direttiva-Farma) Aug 2009
- [www.mrs.org.uk/standards/downloads/2008-01-18/Incentives\\_and\\_Free\\_Prize\\_Draws.pdf](http://www.mrs.org.uk/standards/downloads/2008-01-18/Incentives_and_Free_Prize_Draws.pdf) Aug 2009

## 12 At the Start of Fieldwork

- 12.1 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 (see 11.8):
- 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

## 13 During Fieldwork

### Questionnaire and Question Design

- 13.1 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.

*www.mrs.org.uk/standards/downloads/revise/active/questionnaire\_may06.pdf Aug 2009*

- 13.2 Market research materials must 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

- 13.3 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.
- 13.4 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.
- 13.5 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.

*www.mrs.org.uk/standards/downloads/2006%20Qualitative%20Research%20Guidelines.pdf Aug 2009*

### Stimulus Material

- 13.6 Stimulus material includes any material shown during the course of fieldwork e.g. product profiles, branding concepts, packaging materials.
- 13.7 Stimulus material must be fit for purpose. Pharmaceutical industry codes of practice generally require that information claims and comparisons must be accurate, balanced, fair, objective, and unambiguous, be an up-to-date evaluation of all the evidence and they must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis – the same is expected of stimulus material.
- 13.8 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. The use of brand names when researching hospital products ('H' drugs) with patients **in Italy** although not explicitly forbidden would be considered unethical.
- 13.9 Within any market research care must 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.
- 13.10 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).
- 13.11 All stimulus materials must be collected at the end of the interview.

Additional ABPI guidelines for stimulus material content and format **for the UK** are detailed within the BHBA's Legal & Ethical Guidelines.

### Testing Products and Devices

- 13.12 It is strongly recommended that placebos are used for product testing whenever practical.
- 13.13 Licensed prescription-only medicines can only be taken by a patient if a registered medical practitioner is present. If the product is unlicensed respondents cannot be asked to ingest it without the approval of a Research Ethics Committee.
- The company must provide full product details including all ingredients.
  - Respondents must read and understand the details and must then sign a disclaimer.
- 13.14 If a respondent uses or handles active substance, medication or a medical application which might cause an allergenic or other undesirable effect, usage must be carried out according to Good Clinical Practice (GCP) guidelines.  
<http://www.emea.europa.eu/pdfs/human/ich/013595en.pdf>
- 13.15 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 take normal care of the materials/products when in their possession.

- 13.16 When the client entrusts products to an agency researcher's care, the client commits themselves 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.

*www.esomar.org/uploads/professional\_standards/guidelines/mutual\_rights/Guideline on mutual rights and responsibilities V4\_consultation final.doc Aug 2009*

- 13.17 As with stimulus material, products and devices (active or placebo) must be collected at the end of the interview.

- 13.18 Companies should refer to their medical and regulatory departments for additional guidance.

#### Recording and Observation of Fieldwork

- 13.19 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.

- 13.20 Respondents must be made aware at the time of recruitment if their input is to be recorded or observed, informed consent requires this.

- 13.21 In addition, respondents' written consent for audio or video recording must be obtained at the beginning of the interview before recording commences.

- 13.22 Respondents must be told what will happen to the recording, who (in terms of role/position not names) will see/listen to it and what it will be used for (Data Protection legislation demands this), they must be told this at the start of the study. Where multiple purposes exist or are possible, explicit consent for each purpose should be obtained.

- 13.23 EphMRA recommends that respondents do not introduce themselves by their own name and are not addressed by their own name to help protect their anonymity. Forenames alone or pseudonyms are recommended.

*ADM Guideline Concerning Recording and Observation of Group Discussions and Qualitative Interviews  
www.adm-ev.de/richtlinien Aug 2009*

- 13.24 If a respondent withdraws from the research at any stage e.g. during a group discussion, their contribution must be suppressed from the final analysis and reporting.

- 13.25 Recorded data can only be given to clients if respondents have given their written consent for this. Respondents must be told:

- The name of the recipient company
- To whom it will be given and shown – roles not names
- For what purpose(s) it is likely to be used. Recorded data must not be used for any non-research purpose such as selling or training, without the explicit prior consent of the respondent.

Researchers should ensure that recipients of recordings are aware of their obligations and agree to abide by these.

- 13.26 Recorded data (audio or video) given to clients without respondent permission must be anonymised. It is recognised that audio/video tapes may be difficult to anonymise as an individual's voice/appearance/turn of phrase/opinion may be identifiable, particularly in specialised healthcare fields where the respondent universe is small. **In Germany** if the recording identifies the respondent it cannot be given to the client even if permission was granted.
- 13.27 If the recipient(s) of the recorded data changes after respondents have given permission for its release, the agency must re-contact every respondent and obtain their written permission for further release, giving full details of the people to whom the data will now be shown.
- 13.28 The agency must ensure that the country or organisations in those countries to which any personal data are transferred have adequate data protection measures in place, particularly outside the EU.

#### Observer's Guidelines

13.29 The impact of observers sitting in on groups or interviews should be carefully considered, e.g. when the subject matter or medical condition under discussion is sensitive, the observer's role, gender or age may have an adverse impact. Observers should be advised by the researcher in advance on how to minimise the impact of their presence e.g. through their dress, seating position, role in the group/interview, note taking etiquette etc.

13.30 When client observers are introduced, they do not need to be introduced by name or company name. It is sufficient to tell respondents what type of company they are from, the nature of their roles within that company and in general terms their reasons for observing.

Company name does not have to be revealed unless a respondent asks and then he/she must be told. However, if this information is likely to bias the discussion it may be withheld until the end of the session.

Clients or their sub-contractors must not be passed off as members of the research agency.

- 13.31 Observers must 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 permission 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.
  - Respect the confidentiality of all information exchanged in market research 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.

- 13.32 In circumstances where observers will be watching a video stream in remote locations, the researcher still has a responsibility to ensure that respondents' rights are protected as if the observers were at the research location.

#### Video and audio transmission of fieldwork

- 13.33 When using the services of a company to record, transmit and/or archive audio or video recordings, the commissioning company (whether market research agency or pharmaceutical company) must ensure that:
- Respondent permission for this has been sought and granted in accordance with EphMRA's guidelines (13.19 to 13.32).  
It should be noted that providers of video/audio transmission services generally include a clause in their contracts that make it clear that it is the agency or client's responsibility to secure the appropriate consents and providers assume under the terms of their agreement that the required consents have been procured by the agency/client company before recording, transmission or storage takes place.
  - 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).
  - Respondents are made aware that recordings may be archived for periods of time (1 year) that are longer than is required to fulfil purposes of the study. If the purposes of the study have been completely fulfilled i.e. the purposes of the study are redundant, respondents must give their explicit consent to prolonged storage – this is a data protection requirement.

#### Adverse Event Reporting – Background and Definitions

- 13.34 Suspected adverse reactions associated with any medicinal product must be reported to the relevant authorities. This obligation is defined within EU Directive 2001/83/EC and Regulation 726/2004. Consequently domestic medical authorities such as the FDA in the USA, AIFA in Italy and the CSM in the UK have set in place strict guidelines that must be followed by pharmaceutical companies' pharmacovigilance and drug safety teams.

EphMRA is in complete support of the need to ensure that patients taking a pharmaceutical product are safeguarded from any short or long term adverse effects that could compromise their well-being. EphMRA supports the pharmaceutical companies need to comply with the policies set out by the authorities to try to ensure that any adverse events are reported to the appropriate manufacturer. Balanced against these aspects is the need to ensure that market research, as a discipline is not compromised in being able to continue to offer companies information that is objective and of proven value.

One of the important principles of market research is the need to respect the confidentiality and privacy of the respondent. In situations where there is a request for the identity of the respondent to be passed to a third party for whatever reason, if the respondent refuses permission, then that decision is binding, unless otherwise expressly mandated by law.

An 'adverse event' is any untoward medical occurrence or incident in a patient or clinical-trial subject administered a medicinal product or device, the adverse event does not necessarily have to have a causal relationship with this treatment. An adverse event or incident can therefore be any unfavourable and unintended sign, symptom, disease or incident associated with the use of a medicinal product or device, whether or not considered related to the medicinal product or device. In addition to side effects, the following events need to be reported:

- Exposure during pregnancy or lactation
- Product complaint e.g. the PIL is missing, the inhaler dose counter is faulty
- Unexpected lack of efficacy
- Maladministration/medication errors e.g. patient swallowed a suppository
- Overdose/incorrect dosage, whether accidental or intentional
- Drug abuse/misuse e.g. patients sharing medication
- Accidental exposure e.g. child takes mothers medication
- Drug-drug, drug-food interactions
- Suspected transmission of an infectious agent via a medicinal product
- Identification of a potentially counterfeit medicine

Adverse events must be collected irrespective of whether there is a proven link to the drug or not.

All adverse events potentially associated with the marketing authorisation holder's (MAH) drugs have to be reported not just those associated with the product being researched.

Adverse events that meet the four minimum reporting criteria must be reported. Each of the following four pieces of information must be present to make an event eligible for reporting:

1. An identifiable patient - identified by initials, number, date of birth, age, age group or sex, only one of these identifiers is required to ensure the patient is identifiable.

Although **in the UK**, pharmaceutical companies and their legal agents must now forward all adverse events that are cited in the context of any patient or patients, whether or not a specific identifier is present. Previously a specific identifier was required.

2. An identifiable reporter - the reporter may be identified by name/initials and address or qualification (e.g. doctor, nurse, patient, pharmacist).
3. At least one suspected adverse event.
4. At least one suspected active substance/medicinal product.

If one or more of these four key pieces of information is missing, the event is not 'reportable' and it is not the researcher's responsibility to probe or prompt for the missing information. However if the four key criteria are mentioned then the researcher should prompt the reporting of the event.

#### Adverse Event Reporting – The Procedure

- 13.35 On any occasion where a reportable adverse event occurs during the course of a market research investigation, the respondent must be informed (either at the time of the information being stated or at the end of the interview) that they should inform their physician (in the case of a patient) or the drug company (in the case of a healthcare professional) about the adverse event in question. However, **in Italy**, physicians must report adverse events to the Italian Pharmaceutical Agency (AIFA) and/or their local Health Authority and not to the drug company. In **Germany** physicians should be reminded to report the adverse event to the drug company, the agency should not report the adverse event.

Where companies have their own adverse event reporting procedures, these should be adhered to.

#### Adverse Event Reporting – Time of Response

- 13.36 When conducting face to face (qualitative/quantitative) or telephone interviews, reports of any adverse event occurring, (that relates to an individual patient), should be submitted to the pharmaceutical manufacturer as soon as reasonably possible, preferably within 24 hours (one business day **in the UK**). In the case of internet studies or in other situations where the data on reportable adverse events could not be immediately identified, the same timely response should be followed and begins from the time the adverse event has come to light.
- 13.37 Reports should be sent only to the commissioning client regardless of the country where the adverse event occurred, so that the pharmaceutical company may determine the next reporting steps necessary to comply with the guidelines set out by the medical authorities.

#### Adverse Event Reporting – Training

- 13.38 It is imperative that the market research agencies be informed of their responsibilities with regard to the issue of adverse event reporting by the pharmaceutical company contracting for market research. It is essential that formal training is undertaken to ensure that all those directly involved in data gathering on healthcare issues have a clear understanding of how to recognise an adverse event and whether action is or is not required.

#### Adverse Event Reporting – Syndicated and Audit Data

- 13.39 In those cases where a market research agency is conducting a syndicated investigation on its own initiative, and is offering the data to any potential pharmaceutical company, as the market research agency is not under any legal obligation to provide details of adverse events to the medical authorities, no adverse event reporting is required.

If client specific confidential questions are incorporated into these types of investigations and these lead to an adverse event being mentioned, then the same procedures mentioned at 13.34 for custom market research apply.

If one or more pharmaceutical companies collectively request that a market research agency conduct a 'shared confidential study' for them on an exclusive basis, then the same rules for custom market research apply.

If data, especially diary data is being examined on an aggregate basis then no reporting by pharmaceutical companies or market research agencies is required. If the pharmaceutical company requests patient specific data then the company will need to report any adverse events that are identified **except in the UK**, revised UK Guidelines now require the company to forward adverse event data whether individual patient records or aggregate data are purchased.

With regard to any other audit undertaken by a market research agency if the data collected is able to be purchased by any pharmaceutical company, then as the market research agency is not itself a pharmaceutical company it is not governed by any reporting rules to medical agencies involved in pharmaco-vigilance. Consequently it is not necessary to prepare any adverse event reports at this time.

Additional information upon adverse event reporting is available within the FAQ section.

- 13.40 Collecting Adverse Event Reports **in the UK** – the UK ABPI/BHBIA’s Guidelines state that all organisations and individuals contracted to work on behalf of the commissioning company including market research agencies e.g. interviewers or moderators, are obliged to report adverse events. Consequently researchers have an obligation to record reportable adverse events and report these to the MAH. Revised Adverse Event Reporting Guidelines come into force in the UK from 1 May 2010. The revisions have been incorporated into EphMRA’s Code.
- Full (revised) guidelines and a dedicated training module on UK Adverse Event Reporting Guidelines detailing how to identify and record an adverse event in the UK uncovered during market research project can be found on the BHBIA’s website:  
[www.bhbia.org.uk/Library/ABPIAdverseEventGuidelines/tabid/323/Default.aspx](http://www.bhbia.org.uk/Library/ABPIAdverseEventGuidelines/tabid/323/Default.aspx)
- 13.41 Collecting Adverse Event Reports **in Italy** – ASSIRM (the Italian Market Research Association) states within its *Directive on interviews with medical staff for purposes of market research and social research and public opinion polls* that when face-to-face, postal or online market research is conducted, at the end of the interview physicians must be given a standard text reminding them of their adverse event reporting responsibilities. In the case of telephone interviews the suggested text should be read out. For full details please see:  
[www.assirm.it/index.php?m1=Codici-e-Regole&l1=Direttiva-Farma](http://www.assirm.it/index.php?m1=Codici-e-Regole&l1=Direttiva-Farma)
- 13.42 EphMRA strongly recommends that agencies consult the commissioning company’s adverse event reporting guidelines or the drug safety/pharmaco-vigilance department to ensure that internal adverse event procedures are understood and followed. Company adverse event reporting guidelines should not undermine or limit the requirements set out within EphMRA’s or national guidelines.

## 14 At the End of Fieldwork

### Combining Research Data

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

### Access

- 14.2 Respondents must be made aware that they can ask at any time to know what personally-identified data about them are currently being held and for these to be amended or destroyed.

### Storage Duration

- 14.3 Personal data must be destroyed as soon as the purpose of the study is redundant.
- 14.4 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).
- 14.5 Personal data e.g. contact details should only be stored for future use if permission has been given.
- 14.6 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*

### Security

- 14.7 Researchers are responsible for the safe handling, processing, storage and disposal of market research and personal contact data. The disposal method should be appropriate to the sensitivity and confidentiality of the data.
- 14.8 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.
- 14.9 In addition to Data Protection and HIPAA requirements that personal data be appropriately protected, **in the USA** state legislation can require stringent data encryption and written information security plans for any organisation in the state or holding data of a state resident. Other states are expected to adopt this approach.

### Reporting Market Research

- 14.10 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 technical detail necessary to assess the validity of findings is available (including sample size, question source, statistical tests used) and that data tables include sufficient technical 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.

*www.mrs.org.uk/standards/downloads/revise/active/questionnaire\_may06.pdf Aug 2009*

### Publishing Market Research

- 14.11 The client must not publish any of the results of the survey without the approval of the agency unless otherwise agreed in advance.

- 14.12 **In Spain**, among other requirements, prescription medicines promotional materials must be based on scientific public relevant data and must be referenced. Market research studies not published in renowned scientific/medical publications (i.e. NEJM, Lancet, etc.), cannot be used under any circumstance as references for prescription medicines promotional materials.

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

- 14.14 Full details of the source must be referenced.

- 14.15 **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 members are also required to provide the following additional information if requested:

- Definition of the universe the study is intended to represent and a description of the population frame that was sampled
- Description of the results of the sample implementation e.g. numbers not reached, of refusals, etc.
- Completion rate and how it was calculated
- Description of weighting or estimating, special scoring, data adjustment or indexing procedures
- Estimates of survey or sampling error and how it was calculated
- Interviewer instructions, validation results, code books, and/or other working papers

*CASRO Code of Standards and Ethics for Survey Research, www.casro.org/codeofstandards.cfm*

- 14.16 If research is misrepresented by a client, the researcher must as soon as possible:
- Refuse permission for their name to be used in connection with the misrepresented published findings.
  - Publish a statement that the results have been misrepresented.
  - Publish the necessary information to correct the misreporting.

## E. Respondents' Rights by Research Approach

### 15 Face to Face Methodology

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

### 16 Telephone Methodology

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

- 16.1 To gain the trust of respondents without having the benefit of face-to-face contact, the interviewer must give the name of the agency that he/she represents and must give their own or an agreed contact name. **In the UK**, Market Research Society members must also give the MRS free-phone number and a contact telephone number for the agency at the end of each interview.
- 16.2 **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. 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.  
*www.mra-net.org/ga/resources.cfm?ID=telephone&aID=a1 Aug 2009*
- 16.3 Researchers must 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 must 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.
- 16.4 **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 the UK**, the MRS provides regulations for the use of predictive/auto-diallers.  
*www.mrs.org.uk/standards/downloads/2008-10-28\_Predictive\_Dialler\_Regulations.pdf Aug 2009*

- 16.5 **In Germany** data protection laws prohibit the telephone interviews that are in any way directly linked with telephone marketing. For further details upon telephone interviewing in Germany see Guidelines on Telephone Surveys published by the ADM.  
[www.adm-ev.de/index.php?id=2&L=1](http://www.adm-ev.de/index.php?id=2&L=1)
- 16.6 If using a mobile phone to respond to a market research survey means the respondent incurs a cost this should be reimbursed, researchers must ensure that participating in a market research study does not disadvantage respondents financially.

[www.esomar.org/uploads/professional\\_standards/guidelines/ESOMAR\\_Codes&Guidelines\\_Conducting-survey-research-via-mobile-phone.pdf](http://www.esomar.org/uploads/professional_standards/guidelines/ESOMAR_Codes&Guidelines_Conducting-survey-research-via-mobile-phone.pdf)

## 17 Ethnographic/Observational Approaches

- 17.1 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).
- 17.2 Images of people on film and audio recordings of them would be considered as personal data under Data Protection legislation.
- 17.3 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 must be built in – the right to withdraw must be respected.
- 17.4 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 sufficiently large and readable typeface.
  - Cameras must be sited so that they monitor only the intended areas.

[www.mrs.org.uk/standards/downloads/2006\\_Qualitative\\_Research\\_Guidelines.pdf](http://www.mrs.org.uk/standards/downloads/2006_Qualitative_Research_Guidelines.pdf) Aug 2009

[www.apa.org/ethics/code.html](http://www.apa.org/ethics/code.html) - The Ethical Standards of the American Psychological Association

[www.esomar.org/uploads/pdf/professional-](http://www.esomar.org/uploads/pdf/professional-standards/ESOMAR_Guideline_on_Passive_Data_Collection_November2008_.pdf)

[standards/ESOMAR\\_Guideline\\_on\\_Passive\\_Data\\_Collection\\_November2008\\_.pdf](http://www.esomar.org/uploads/pdf/professional-standards/ESOMAR_Guideline_on_Passive_Data_Collection_November2008_.pdf) Aug 2009

## 18 Internet

### Background and Definitions

- 18.1 Internet research currently refers to research in which a respondent – either on a single or successive occasions – is involved in any of the following:
- Completing research documentation online via the internet regardless of access route
  - Downloading research documentation from a server on the internet and returning it by email
  - Receiving research documentation incorporated into an email and returning it the same way
  - Participating in an online qualitative interview or discussion
  - Taking part in a measurement system which tracks web usage using specialist software installed on the user's computer.
  - 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

*[www.mrs.org.uk/standards/internet.htm](http://www.mrs.org.uk/standards/internet.htm)*

EphMRA's guidelines also apply to research conducted via Personal Digital Assistants (PDAs), Wireless Access Protocol (WAP), webcams and third generation (3G) technology.

- 18.2 An internet 'access panel' is defined as a sample of potential respondents who declare that they are willing to receive invitations to participate (if selected) in future internet interviews. Further guidance for research suppliers setting up and managing internet panels are available from ESOMAR at *[www.esomar.org/index.php/26-questions.html](http://www.esomar.org/index.php/26-questions.html)*. These cover panel recruitment, project management, monitoring, maintenance and data protection issues. CASRO also include panel considerations within their Code of Standards and Ethics for Survey Research. *[www.casro.org/codeofstandards.cfm](http://www.casro.org/codeofstandards.cfm) Aug 2009*

- 18.3 A respondent's email address is personal data where it refers to an individual and therefore needs to be protected in the same way as other identifiers.

- 18.4 **In the UK** market research emails are not defined as commercial communications within the 2003 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.

### Key Points

- 18.5 Researchers must avoid intruding unnecessarily on the privacy of internet respondents.
- 18.6 Respondents must be alerted to any costs they may incur e.g. online charges.
- 18.7 Respondents must be told of the researcher's identity and given contact details. They must 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.

- 18.8 Researchers must use adequate technologies to protect the personal data collected or stored on websites or servers.
- 18.9 Researchers must post a privacy policy statement on their website. The statement should be easy to find, easy to use and comprehensible, including by children when appropriate.
- In the USA** if a company fails to adhere to the privacy policy it posted online it is a federal offence under section 5 of the Federal Trade Commission Act.
- A guide to privacy policies, their standard elements and an example privacy policy is provided within ESOMAR's Guideline on Conducting Marketing and Opinion Research using the Internet [www.esomar.org/uploads/pdf/ESOMAR\\_Codes&Guideline-Conducting\\_research\\_using\\_Internet.pdf](http://www.esomar.org/uploads/pdf/ESOMAR_Codes&Guideline-Conducting_research_using_Internet.pdf) Aug 2009
- 18.10 Cookies store specific information about online browsing. EU legislation (passed late 2009 and to be enacted in to national legislation by April 2011), 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 - **in the UK** this is a legal requirement in accordance with the Privacy and Electronic Communications Regulations. ).
- 18.11 Links to data protection; privacy policy or cookie consent statements must be given at the start of the questionnaire. This will ensure that should respondents fail to complete the questionnaire for any reason their rights are protected.
- 18.12 For surveys completed online, respondents must 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).
- 18.13 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.
- 18.14 Researchers must not use unsolicited emails (spamming) to recruit market research study respondents. Individuals contacted must have a reasonable expectation that they will receive email contact for market research. This expectation should be based upon a substantial pre-existing relationship that would lead the individual to expect market research contact by email and it should give them the choice to be excluded from future invitations and if they decide to exclude themselves ensure that this is respected.
- When receiving email lists agencies must verify that individuals listed have a reasonable expectation they will be contacted by email for market research purposes.
- It is suggested that either:
- Active opt-in whereby respondents actively agree to participate, in which case no confirmation is required as to their future status as potential participant
  - or
  - Confirmation by the respondent of opting-in status is required. Subsequent communication without this confirmation would be considered a spam.

**In the USA** the Federal CAN SPAM Act and CASRO's mandatory Code of Standards requires prior permission from individuals to be contacted via their email addresses. The CASRO Code prohibits agencies from using unsolicited emails to recruit survey respondents or engage in surreptitious data collection methods. [www.casro.org/codeofstandards.cfm](http://www.casro.org/codeofstandards.cfm) Section I.B.3

- 18.15 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.
- 18.16 Internet studies must provide either the client's identity or an opportunity to ask for it, at an appropriate point within the study - the client's identity must be given if sampling from a customer database (i.e. the client supplied a list of potential respondents) or if it is directly requested. It is important to ensure that if a respondent withdraws from an internet interview before it is complete, they should still be provided with an opportunity to ask for the identity of the client company.
- 18.17 **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 2001*
- 18.18 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).
- 18.19 Clients must be made aware of the potential risks of using confidential information in internet 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.

For additional guidance on research with children/young people using the internet, see 21.5 and 21.6

Using identification and tracking technologies/software for market research purposes

- 18.20 Respondents must always be told at the first opportunity when software is being used to collect information about them (sometimes referred to as spyware or, malware if used covertly), 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 permission 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 2010.

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

Within its Guidelines for Online Research 2010 ESOMAR details a series of 17 'Unacceptable Practices' that researchers must forbid or prevent. EphMRA members are referred to this list for further information.

**For the USA** CASRO provides detailed guidelines with regard to the use of active agent technology within its Code of Standards and Ethics. [www.casro.org/codeofstandards.cfm#sectionI.B.3](http://www.casro.org/codeofstandards.cfm#sectionI.B.3) Aug 2009

#### Internet Access Panels

- 18.21 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 internet interviews. At recruitment potential panel members must be told that their personal may be stored for further market research.
- 18.22 ESOMAR provides a series of guidelines on internet access panels, covering panel recruitment, management, monitoring, maintenance and privacy/data protection, as well as a battery of 26 Questions to help research buyers. These guidelines and the question battery can be found at [www.esomar.org/uploads/pdf/ESOMAR\\_Codes&GuidelineConducting\\_research\\_using\\_Internet.pdf](http://www.esomar.org/uploads/pdf/ESOMAR_Codes&GuidelineConducting_research_using_Internet.pdf) section 4, pages 17 to 23. Aug 2009

#### Social Media

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."

- 18.23 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 permission. Researchers should ensure that they abide by the terms and conditions attached to use of site content.
- 18.24 Care must be taken to ensure that apparently anonymous quotations are indeed anonymous and cannot be traced back to reveal their original source.
- 18.25 ESOMAR has proposed the following classification of social media space:

**Public space** - a place where content is contributed with the assumption that it could be read by anyone in the public and where contributors could not be surprised that it is linked to/copied/cited. Examples include many public blogs or comments left on news websites.

**Semi-public space** - a place where people contribute content which although technically open to all to read, many would not expect it to be read or used by people not involved in the specific topic or conversation.

The boundary between public and semi-public space is open to interpretation and researchers are encouraged to act with caution and regard sites as 'semi-public' if they have doubts. Examples include Facebook home pages and many niche (but open) forums/communities. It also includes all forms of open synchronous online activity e.g. open chatrooms, Twitter, etc.

**Private space** - a place where most users would expect their comments to be private and which is available only to genuine community members. They are often called ‘walled gardens’ as they can only be accessed after the user has obtained a login and/or password, even if entry is automatic. Examples include many private forums, communities and chatrooms as well as instant messaging.

**Specific market research space** - an online place specifically created for market, social and opinion research purposes where users have been informed of its function and the use to which their comments might be put. Typically (but not always) these are also private spaces. Examples include Market Research Online Communities (MROC’s).

*ESOMAR Guideline on Social Media Research, Consultation Draft, Feb 2011*

The following guidelines apply within each type of ‘space’:

**Public space** - may be used by researchers, although it may be necessary to ‘cloak’ comments if they could be in any way harmful to the individual (e.g. embarrassing). Cloaking means altering information so that it cannot be traced back to the contributor.

**Semi-public space** – researchers should not pass on any identifiable information.

**Private space** – market research can only take place with the consent of the service provider. Researchers should announce their presence and seek the co-operation of site participants. Researchers must gain the consent of participants to quote them and without this consent, all comments should be cloaked. Researchers must not pose as an ‘ordinary’ participant e.g. on a patient website to gather information - their role and purpose must be transparent.

**Specific market research space** – The same guidelines apply to these as to other forms of internet market research.

### Using Social Media Space for Market Research Purposes

Space	Available for researchers	Identifiable in reports	Cloaking of verbatim quotes in reports
<b>Public space</b>	Yes, subject to service Terms of Use	Yes, except if might cause harm	No, only required if it might cause harm
<b>Semi-public space</b>	Yes, subject to service Terms of Use	No, except with user permission	More likely to be required than a public space and essential if it might cause harm
<b>Private space</b>	Only with permission of service	No, except with user permission	Essential unless user gives permission to cite
<b>Market research space</b>	Yes	Possible, subject to sign up agreement	No, only required if it might cause harm

Source: *ESOMAR Guideline on Social Media Research, Consultation Draft, Feb 2011*

## F. Respondents' Rights by Respondent Type

### 19 Patients

- 19.1 When researching existing or future potential medical treatments with patients, care must 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 Simulated consultations between a patient and a healthcare professional (known or unknown to each other) are a legitimate research approach however they must 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.

#### Patient Data

- 19.3 As previously detailed in 6.1, **in the USA**, the HIPAA Privacy Rule gives the individual rights over their health information and sets limits upon who may access this information. An individual's health information cannot be used or shared with anyone other than the Covered Entity's Business Associates without the individual's written permission for non-health care related purposes (although there are some specific exceptions). There is no restriction upon the use of protected health information if it has been de-identified in accordance with the standards set by the Privacy Rule. There are two ways to de-identify data. The 'safe harbor' method is to remove all 18 identifiers enumerated within section 164.514(b)(2) of the regulations:
- (A) Names
  - (B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
  - (C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
  - (D) Telephone numbers;
  - (E) Fax numbers;
  - (F) Electronic mail addresses;
  - (G) Social security numbers;
  - (H) Medical record numbers;
  - (I) Health plan beneficiary 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.

*www.hhs.gov/ocr/privacy/index.html Aug 2009*

*Summary of the HIPAA Privacy Rule, U.S. Department of Health & Human Services,*

*edocket.access.gpo.gov/cfr\_2002/octqtr/pdf/45cfr164.514.pdf Aug 2009*

## **20 Vulnerable Respondents**

- 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.
- 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 **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.

## **21 Children and Young People**

- 21.1 When conducting research with children or young adults, a 'child' is a minor 15 years old or less and a 'young person' is 16 or 17 years of age. Although **in Sweden**, children are defined as 14 years or younger and in **Germany**, a child is minor 13 years old or less and a young person is 14 to 17 years of age.
- 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 (acting in loco parentis) must be obtained before interviewing a child under 16 in the following circumstances:
- In home/at home (face-to-face and telephone interviewing)
  - Group discussions/depth interviews
  - Postal questionnaires
  - Internet questionnaires
  - 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

- 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 the research is conducted via the internet, a notice to children informing them of the requirement for consent must be shown at the point where personal information is requested.
- 21.4 Details of the person giving consent (name and role) must be recorded.
- 21.5 EphMRA recommend that online research is not conducted with children under the age of 14.
- 21.6 For research administered via the internet, when it is known (or ought reasonably to be known) that all or most of the respondents are likely to be under 16, respondents must be asked to give their age before any other personal information is requested. If the age given is under 16, the child must be excluded from giving further personal information until the appropriate consent from a parent or responsible adult has been obtained and verified.
- 21.7 **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. The rule 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.  
*MRA’s Code of Marketing Research Standards, Appendix B: How to comply with the Children’s Online Privacy Protection Bill Aug 2009*  
[www.coppa.org/comply.htm](http://www.coppa.org/comply.htm) Aug 2009  
[www.ftc.gov/kidzprivacy](http://www.ftc.gov/kidzprivacy) Aug 2009
- 21.8 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.
- A notice to the parent/responsible adult must be placed on the website or sent via email asking for their consent for the child to participate in internet-based market research. ESOMAR provide guidelines upon the recommended content of such a notice.  
[www.esomar.org/uploads/pdf/ESOMAR\\_Codes&Guideline-Conducting\\_research\\_using\\_Internet.pdf](http://www.esomar.org/uploads/pdf/ESOMAR_Codes&Guideline-Conducting_research_using_Internet.pdf), page 15. Aug 2009
- 21.9 No study can ask a child to do something illegal for their age.
- 21.10 Language on questionnaires must be suitable for the age group.
- 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.
- 21.12 If children/young people are to be asked to take part in any form of product or device testing, researchers must take special care to ensure that:
- The products/devices are safe to handle or consume
  - The child/young person does not suffer from any relevant allergy
  - EphMRA recommends that active medicines are not used in market research testing with children

- 21.13 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.
- 21.14 The researcher should ensure that the responsible adult has full details of the research venue, name of moderator, finishing time, etc.
- 21.15 Where incentives are used they should be suitable and acceptable for the age of the child/young person and fitting for the task required.
- 21.16 The researcher should take responsibility for safely handing over the child/young person after a group discussion or depth interview or ensuring that arrangements for them to get home safely are in place.
- 21.17 Interviewers who will have contact with children should be checked against national/local databases, as appropriate in each country.

*[www.mrs.org.uk/standards/downloads/revise/active/children\\_young\\_people\\_mar06.pdf](http://www.mrs.org.uk/standards/downloads/revise/active/children_young_people_mar06.pdf) Aug 2009*

*[www.esomar.org/uploads/pdf/ESOMAR\\_Codes&Guideline-Conducting\\_research\\_using\\_Internet.pdf](http://www.esomar.org/uploads/pdf/ESOMAR_Codes&Guideline-Conducting_research_using_Internet.pdf) Aug 2009*

## **22 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.
- 22.2 Normally a senior member of the marketing or clinical department would 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.

## **23 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.

## **24 Payers and Influencers**

- 24.1 Given the potentially sensitive nature of discussions with payers and influencers, care must 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 13 Sensitive Topics (13.3, 13.4 and 13.5).

## G 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 would then be referred to the appropriate regulatory body, following which disciplinary measures may be taken if appropriate.
- 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

**Agency** – any individual, organisation or department, including any belonging to the same organisation as the client which is responsible for, or acts as, a supplier on all or part of a market research project.

**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.

**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.

**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.

**Interviewer** – The person who collects data from respondents for market research purposes.

**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.

**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.

**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) under the instruction of the researcher.

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

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](http://www.ephmra.org)

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## Appendices

### California

The law requires pharmaceutical companies that do business in California adopt comprehensive compliance programs that is in accordance with the “Compliance Program Guidance for Pharmaceutical Manufacturers” which was developed by the U.S. Department of Health and Human services Office of Inspector General (OIG). The compliance program shall include policies for compliance with the Pharmaceutical Research and Manufacturers of America’s (PhRMA) “Code on Interaction with Healthcare Professionals”.

The law requires each pharmaceutical company to establish in its compliance program a specific annual dollar limit on gifts, promotional materials, or items or activities that the pharmaceutical company may give or otherwise provide to an individual medical or health care professional in accordance with the “Compliance Program Guidance for Pharmaceutical Manufacturers” and with the “Code on Interactions with Health Care Professionals”.

Excluded from the limits are

- Drug samples given to physicians and health care professionals intended for free distribution to patients, financial support for continuing medical education forums, and financial support for health educational scholarships if such support is provided in a manner that conforms to the OIG compliance program and the PhRMA code.
- Payments made to legitimate professional services provided by a health care or medical professional, including, but not limited to, consulting, are exempt from any limits, provided the payment does not exceed the fair market value of the services rendered and the payments are provided in a manner that conforms to the OIG compliance program and the PhRMA code.

### District of Columbia

The law requires manufacturers and labelers to disclose and file annual reports of all prescription drug marketing costs, with some exceptions. The report shall specify the value, nature, purpose and receipt of expenses for:

- all advertising, marketing and direct promotion;
- with respect to all persons or entities licensed to provide health care in the state, the report shall specify the cost of education or information programs, food, entertainment, gifts valued at more than \$25, trips and travel; and product samples, except for free patient samples.

Excluded from the reporting requirements are:

- marketing expense of \$25 or less per day per health care provider or entity;
- reasonable compensation and reimbursement for expense in connection with a bona fide clinical trial for a new vaccine, therapy, treatment, or indication;
- scholarships and reimbursement of expenses for attending a significant education, scientific or policy-making conference or seminar of a national, regional, or specialty medical or other professional association if the recipient is chosen by the association sponsoring the conference or seminar; and
- expenses associated with advertising an promotional activities purchased for a regional or national market that includes advertising in the District if the portion of the costs pertaining to or directed at the District or cannot be reasonable allocated, distinguished, determined or otherwise separated out.

## Maine

In 2003 Maine passed LD 254/H 209 that requires manufacturers or labelers of prescription drugs to file annual reports with the department of Human Services which shall specify the "value, nature, purpose, and recipient expenditures" for:

- A. All advertising expenses;
  - B. With regard to all persons and entities licensed to provide health care in the State, the cost of:
    - 1. educational or informational programs;
    - 2. food, entertainment, gifts valued at more than \$25;
    - 3. trips and travel; and
    - 4. product samples, except for free patient samples;
  - C. The aggregate cost of all employees or contractors of the manufacturer or labeler who directly or indirectly engage in the advertising or promotional activities listed above, including all forms of payment to those employees within the state
- Exemptions: expenses of \$25 or less; compensation and reimbursement of expenses for bona fide clinical trial activities; and scholarships and expenses for attending educational or policy conferences if the attendee was chosen by the sponsoring organization.

In 2005 Maine passed three laws addressing pharmaceutical marketing and direct-to-consumer advertising:

LR 487/LD 1618: prohibits pharmaceutical companies from advertising on television, radio or in print unless the material meets federal guidelines; includes clinical trial requirements that manufacturers "shall post on the public website of the federal National Institutes of Health or another publicly accessible website information concerning any clinical trial that the manufacturer conducted or sponsored beginning October 15, 2002; and includes a fee for prescription drug manufacturers that advertise in the state for maintaining the clinical trial database.

LR 1703/LD 1539: limits the pricing information that a pharmaceutical manufacturer must report to the state the average manufacturer price (AMP) and the best price as defined by federal law; eliminates the instructions on calculating other pharmaceutical pricing information and the requirement to describe the methodology for calculating pricing information that is reported; and strengthens the confidentiality protections afforded to the reported information.

LR 1703/LD 1541: delays implementation of the deadline for filing reports regarding marketing activities by pharmaceutical manufacturers; and clarifies that the Department of Health and Human Services may disclose that information to an entity that provides services to the department under the laws requiring those reports, but specifies that such disclosure does not change the confidential status of the information.

## Massachusetts

In 2009 Massachusetts approved regulations which established a code of conduct for pharmaceutical and medical device manufacturers ("Code of Conduct"). The Code of Conduct was implemented for the purpose of preventing undue influence by pharmaceutical and medical device manufacturers on health care practitioners. The regulations require pharmaceutical and medical device manufacturers to (a) implement certain policies with respect to non-patient identified prescriber data, (b) adopt a code of conduct which prohibits certain activities and (c) disclose certain financial interactions between the company and covered recipients.

## Code of Conduct

The Code of Conduct prohibits:

- Payments for entertainment or recreational items of any value;
- Payments of any kind including cash or cash equivalent made directly or indirectly, except as compensation for bona fide services;
- Giving, directly or indirectly, of any tangible items regardless of value (including token items such as pens, coffee mugs, gift cards, etc.) except as compensation for bona fide services;
- Any grants, scholarships, subsidies, consulting contracts, or educational or practice related items in exchange for prescribing, disbursing, or using prescription drugs, biologics or medical devices;

Meals are restricted and in some instances prohibited. Generally, meals provided to health care providers must be modest and occasional in nature and can not occur outside the practitioner's office or hospital setting. The Code of Conduct prohibits meals that:

- Are part of an entertainment or recreational event;
- Are offered without an information presentation made by the company;
- Are provided to a healthcare practitioner's spouse or other guest.

The Code of Conduct prohibits the payment, either directly or indirectly, for expenses associated with any CME event, third-party scientific event or educational conferences or professional meetings. Such expenses include

- Travel, lodging, meals, or other personal expenses;
- Compensation for time spent at the event;
- Sponsorship or payment for CME events that do not meet the Standards for Commercial Support as established by the Accreditation Council for Continuing Medical Education (ACCME) or its equivalent.

Permissible payments include:

- Compensation or reimbursement made to a health care practitioner serving as a speaker or providing actual and substantive services as a faculty organizer or academic program consultant for a CME or similar event, provided the payment:
  - Is reasonable;
  - Is based on fair market value; and
  - Complies with the standards for commercial support as established by the relevant accreditation entity.
- Sponsorship or payment for third-party scientific or educational conference, or professional meetings which are made directly to the conference organizers.

## Financial Disclosure

Beginning July 1, 2010, and annually on or before July 1 of each year thereafter, every pharmaceutical and medical device manufacturing company must disclose the value, nature, purpose and recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50, which the company provides, directly or through its agents, to any person authorized to prescribe, dispense or purchase prescription drugs, biologics or medical devices in the commonwealth in connection with the company's sales and marketing activities.

For purposes of computing the \$50 threshold, fees, payments, subsidies and other economic benefits relating to separate events or transactions shall be calculated on an individual transactional basis and shall not be aggregated. Pharmaceutical or medical device manufacturing companies shall not

structure fees, payments, subsidies or other economic benefits to health care practitioners to circumvent the reporting requirements.

All information provided under this disclosure requirement will be posted on a searchable, publicly available website.

## Minnesota

In 1993 Minnesota passed a law which prohibits manufacturers or wholesale drug distributor, and their agents from giving any gift of value to a practitioner. A "gift" does not include:

1. professional samples of a drug provided to a prescriber for free distribution to patients;
2. items with a total combined retail value, in any calendar year, of not more than \$50;
3. a payment to the sponsor of a medical conference, professional meeting, or other educational program, provided the payment is not made directly to a practitioner and is used solely for bona fide educational purposes;
4. reasonable honoraria and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting;
5. compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project;
6. publications and educational materials; or
7. salaries or other benefits paid to employees.

## Vermont

In 2009 Vermont passed a more restrictive pharmaceutical marketing law, banning gifts to physicians from industry. The law makes it unlawful for any manufacturer of a prescribed product or any wholesale distributor of medical devices, or any agent thereof, to offer or give any gift to a healthcare provider.

"Gifts" are defined as:

- Anything of value provided for free;
- Any payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care professional, unless:
  - It is an allowable expense as defined by the statute
  - The healthcare provider reimburses the cost at fair market value

"Allowable Expenditures" include:

- Payment to the sponsor of a significant educational, medical, scientific, or policy-making conference or seminar, provided:
  - (i) the payment is not made directly to a health care provider;
  - (ii) funding is used solely for bona fide educational purposes; and
  - (iii) all program content is objective, free from industry control, and does not promote specific products.

- Honoraria and payment of the expenses of a health care professional who serves on the faculty at a bona fide significant educational, medical, scientific, or policy-making conference or seminar, provided:
  - (i) there is an explicit contract with specific deliverables which are restricted to medical issues, not marketing activities; and
  - (ii) the content of the presentation, including slides and written materials, is determined by the health care professional.
- For a bona fide clinical trial.
- For a research project that constitutes a systematic investigation, is designed to develop or contribute to general knowledge, and reasonably can be considered to be of significant interest or value to scientists or health care professionals working in the particular field of inquiry.
- Payment or reimbursement for the reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual health care professionals on the use of a medical device if the commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the health care provider and the manufacturer.
- Royalties and licensing fees paid to health care providers in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the health care provider holds an ownership right.
- Other reasonable fees, payments, subsidies, or other economic benefits provided by a manufacturer of prescribed products at fair market value.

## West Virginia

In 2004 West Virginia enacted a law requiring the reporting of pharmaceutical advertising costs. The law requires advertising costs for prescription drugs, based on aggregated national data, be reported to the state by all manufacturers and labelers of prescription drugs dispensed in the state that employs, directs or utilizes marketing representatives. The following are exempt from the disclosure requirements:

- All free samples of prescription drugs intended to be distributed to patients;
- All payments of reasonable compensation and reimbursement of expenses in connection with a bona fide clinical trial; or
- All scholarship or other support for medical students, residents and fellows to attend significant educational, scientific or policy-making conference of national, regional or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.

The US Marketing Research Association provides a 'Respondent Bill of Rights' which details respondents' rights when interviewed - [www.mra-net.org/rq/practices.cfm?ID=bill](http://www.mra-net.org/rq/practices.cfm?ID=bill) Aug 2009

## **Respondent Bill of Rights**

What Your Rights Are If You Are Interviewed:

Your participation in a legitimate public opinion research survey is very important to us, and we value the information you provide. Therefore, our relationship will be one of respect and consideration, based on the following practices:

- Your privacy and the privacy of your answers will be respected and maintained.
- Your name, address, phone number, e-mail, personal information, or individual responses will not be disclosed to anyone outside the research project without your permission.
- You will always be informed in advance if an interview is to be audio recorded or video recorded (as in the case of telephone or in-person studies). Additionally, you will be told of the intended use of the recording.
- Upon request, you will be informed of the privacy policy that applies to your participation in the research study.
- The researcher will be identified to you. You will be told the name of the research organization and the general nature of the survey.
- You will not be sold anything, or asked for money, under the guise of research.
- You will be contacted at reasonable times, but if the time is inconvenient, you may ask to be re-contacted at a more convenient time.
- Your decision to participate in a study, answer specific questions, be re-contacted at another time, or discontinue your participation will be respected.
- You are assured that the highest standards of professional conduct will be upheld in the collection and reporting of information you provide.

Recruitment Agreement	
Project Title:	Project No:
<b>Nature of Project</b>	
Subject and purpose of market research study:	
Methodology and Approach	
<b>Fieldwork</b>	
Location:	Duration:
Date:	Start Time:
<b>Incentive</b>	
Type: (e.g. cash or vouchers etc.)	Amount:
<b>Respondent Signature</b>	
Signature:	Name (please print)
<b>Respondent Code Number</b>	
Code Number	

<b>Receipt of Incentive</b>	
<b>Project Details</b>	
Project Title:	Project No:
Agency:	Agency Contact:
<b>Fieldwork</b>	
Date:	Start Time:
Location:	Duration:
<b>Incentive</b>	
Incentive Type: (e.g. cash or vouchers etc.)	Incentive Amount:
<b>Declaration</b>	
<p>I confirm that the information I have given during the course of this interview/group discussion was correct and represents my views on the subject matter.</p> <p>I confirm that I have received the incentive detailed above as a token of appreciation for my time and contribution to the project.</p>	
<b>Respondent Signature</b>	
Signature:	Name (please print)
<b>Respondent Code Number</b>	
Code Number	

<b>Respondent Permission Allowing Client Access to Recordings of Market Research Fieldwork</b>	
<b>Project Details</b>	
Project Title:	Project No:
Agency:	Location of Fieldwork:
Date of Fieldwork:	Start Time of Fieldwork:
<b>Declaration</b>	
<p>I understand that _____ (company name) will have access to recordings of this market research interview/group discussion.</p> <p>I understand that the purpose(s) of the company having access is:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>The people in the company who will listen to or view the recordings will be in the following functions/roles:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>And the recording(s) will be in the secure care of: _____</p> <p>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.</p>	
<b>Signatures</b>	
Respondent Signature:	Name (please print)
Agency Signature:	Name (please print)
<b>Respondent Code Number</b>	
Code Number	

<b>Client Agreement to Safeguard Confidentiality of Recordings of Market Research Fieldwork</b>	
<b>Project Details</b>	
Project Title:	Project No:
Agency:	Location(s) of Fieldwork:
Date(s) of Fieldwork:	Start Time(s) of Fieldwork:
Commissioning Client Company	
<b>Declaration</b>	
<p>On behalf of the commissioning client company I can confirm that the recording(s) of market research fieldwork from the above study will only be used for the following purpose(s):</p> <p>_____</p> <p>_____</p> <p>The only people in the company who will listen to or view the recordings will be in the following functions/roles:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>And the recording(s) will be in the secure care of: _____</p> <p>On behalf of the commissioning client company I can confirm that:</p> <ul style="list-style-type: none"> <li>– Those listening to or viewing the recording will respect the confidentiality of all information exchanged in market research interviews/groups</li> <li>– No sales approaches will ever be made to respondents as a consequence of the company having this access.</li> <li>– No attempt will be made to reverse the anonymisation</li> <li>– The recordings will be destroyed or handed back to the agency as soon as is required.</li> </ul>	
<b>Signatures</b>	
Company Signature:	Name (please print)
Agency Signature:	Name (please print)

<b>Observer Agreement</b>	
<b>Project Details</b>	
Project Title:	Project No:
Agency:	Agency Contact:
Location of Fieldwork:	Date of Fieldwork:
	Time of Fieldwork
<b>Declaration</b>	
I understand that I must be familiar with and adhere to the EphMRA's Observers' Guidelines.	
<b>Observer Signature</b>	
Signature:	Name (please print)

**Observers' Guidelines**

Client observers must be introduced openly and honestly to respondents. Actual company identity does not have to be explicitly revealed unless a respondent asks and then he/she must be told. However, if this information is likely to bias the discussion it may be withheld until the end of the session. 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 permission 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.

## Frequently Asked Questions - FAQs

Question	Answer
<p><b>Source of respondent names</b>  <i>We are currently conducting a research project which involves recruiting patients who are listed on a patient database. They were added to the database when they sign up to a company-sponsored patient support programme. They all agreed to participate in market research at point of enrollment. What must we say if the patient asks where their name was obtained?</i></p>	<p>If at recruitment or any point thereafter, the respondent wishes to know how or where their name was obtained they must be told of the source i.e. they must be told that their name was chosen from the patient support programme database, it is allowable to cite this source without naming the sponsoring company; they need not be told until the end of the interview who the company is sponsoring the research if they want to know this – these are two separate pieces of information.</p>
<p><b>Inaccurate recruitment details</b>  <i>I'm recruiting respondents from a client-supplied list of GPs. Some of the details on the list turn out to be inaccurate or false and the client is insisting on being notified of which entries are incorrect. What should I do?</i></p>	<p>Information about incorrect addresses and deaths can be passed back but the correct addresses can only be supplied with the express permission of the respondent. In future it may be worthwhile for researchers to include in their contracts a clause to the effect that they will not pass back any information on individuals or the lists. The EU Data Protection Directive stipulates that personal data should be accurate and up to date. Therefore if a large number of inaccuracies are found the client should conduct a data cleansing exercise.</p>
<p><b>Recruitment agreement</b>  <i>We have spoken to our recruitment agency about the requirement to get consultants to sign an agreement prior to conducting face to face interviews. Their position is that they get a read receipt to their email indicating that the respondent has read the information regarding the interview details and this is sufficient to comply with Article 14, is this correct?</i></p>	<p>EFPIA's Article 14 and EphMRA's Code of Conduct require that a written contact or agreement be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis of those services. So members should document an agreement between agency or company (this can be a recruiter provided the services of the recruiter are contracted to the agency) and the healthcare professional at recruitment that specifies:</p> <ul style="list-style-type: none"> <li>– the respondent has agreed to participate in a MR study</li> <li>– study objective</li> <li>– methodology</li> <li>– date and time of fieldwork</li> <li>– expected duration and fieldwork location</li> <li>– nature and rate of remuneration.</li> </ul> <p>A read receipt email would not be sufficient to meet these needs.</p>

<p><b>Recruitment agreement</b>  <i>Can we obtain the recruitment agreement for panelists – as required by EFPIA’s Article 14 - as a one-off rather than before each survey; on the understanding that panelists receive all the required survey details upon invitation,?</i></p>	<p>Yes, agencies can obtain recruitment (Article 14) agreement from panelists as a one-off, on the understanding that they receive all the required information upon invitation, rather than before each survey.</p>
<p><b>Including the product name</b>  <i>Can we test a product profile or communication material with the product name <u>or</u> the molecule name on it when the product has not yet been launched and has not yet obtained a specific indication that is put in the profile?</i></p>	<p>The use of product names, brand or generic is not prohibited however the use of a name does have to be deemed necessary to meet the (valid) research objectives otherwise its use may be considered disguised promotion. This guideline applies equally to brand and generic names, in pre-launch and post-launch situations. If the use of the name is necessary to full and proper interpretation of the stimulus material, and use of this material is necessary to meet the study’s objectives then use of a name would be reasonable. Unnecessary use of brand names, over-emphasis of claims and product messages is not appropriate and could be considered disguised promotion.</p>
<p><b>Remote observation</b>  <i>My clients can view groups remotely via the Internet through a secure password protected channel. The client could view from a laptop anywhere and so someone else could view the group. What should be done to ensure that respondent confidentiality is protected?</i></p>	<p>Firstly the respondent must be informed and must agree to the group being viewed in this way. Secondly your contract with the client who is to observe must stipulate that all viewing is conducted in a manner which could ensure that no-one outside the project team would have sight of the group.</p>
<p><b>Use of video-clips</b>  <i>Can we include video-clips from patient group discussions in agency presentations to clients and for their further use on the client's internal network?</i></p>	<p>Video-clips can be shown to clients as long as written permission for their specific use has been given by each respondent in the groups before the video recording begins. If they were to be used later on the client's internal network/ intranet then permission for that would have to be sought as well, but this permission must be sought prior to or at the time of interview and not after the event unless you have permission to re-contact the respondent to gain additional consent. The agency should at the same time obtain written assurance from the client that the use of such video-clips would be limited to the uses specified to respondents.</p>

**Investigation of complaint**

*If a complaint is made with regard to the actions of an agency in a single country within a multi-country study, who would follow this up – EphMRA or the local MR body?*

If the complaint was made to EphMRA, EphMRA would investigate the complaint, if the complaint was made to the local MR body, they would be within their rights to investigate. Local guidelines apply irrespective of whether the work was commissioned from the UK or from overseas.

Questions and answers that relate to adverse event reporting for market researchers in both pharmaceutical companies and market research agencies

Question	Answer
<p>1. <i>Why does MR have to become involved in AE reporting?</i></p>	<p>A MR agency is, when asked to become involved in custom research project, acting as an agent for the pharma company, however they are not necessarily bound to report AEs as part of their contract unless this is specified.</p> <p>Some pharmaco-vigilance personnel require anyone working for the company to report any AE that is mentioned, where the AE is directly linked to an individual patient, which means that MR agencies along with other similarly employed organisations (advertising agencies, CROs etc) have to act in accordance with the legally enforceable rules of the pharma company.</p> <p>However, there are several companies that appear to feel that as the information collected via MR interviews is not based on any scientific clinical investigations and that the information provided is “soft”. Not all feel there is a need to involve MR agencies in such types of reporting. This is why several different points of view exist.</p>
<p>2. <i>What should I do if senior staff in a pharma’ company ask that only physicians who consent to allow their names to be passed on to the company if an AE linked to a patient for the company’s product is mentioned?</i></p>	<p>EphMRA along with many other organisations, including the BHBlA and the ABPI in the UK all believe that it is unnecessary to adhere to such a request.</p> <p>It should be pointed out that many pharma company pharmaco-vigilance directors also believe that if a doctor that has been interviewed and a relevant AE has been mentioned in an interview, should the doctor refuse to allow his/her name to be passed onto the company, it is sufficient to report the event without naming the physician. This is still a reportable event and can be submitted to the FDA or other relevant body. In Germany it is not possible to pass on the name of the respondent to any third party for any reason (See ADM market research guidelines).</p> <p>If the company insists on such a procedure, it would be up to the agency to decide either to comply or to refuse the project. The EphMRA Guidelines cannot be regarded as legally binding.</p>

<p>3. <i>In Germany, the ADM and BVA has indicated that physician confidentiality is sacrosanct and studies that require the physician's name to be passed onto a pharma' company in the event of an AE having to be reported should not be undertaken by a German MR agency or fieldwork organisation. What can be done in this situation?</i></p>	<p>The pharma company will need to be advised of this situation. They can decide either to drop Germany from the range of countries to be examined, or they can be informed that a statement similar to the one in the EphMRA Guidelines will be shown to the physicians advising them of their obligation to report such an event to the pharma company's Drug Safety department. If this is acceptable then the study could proceed, if not the study may not be feasible in Germany.</p>
<p>4. <i>If an agency is asked to conduct a multi-country study, what procedure on AE reporting should there be given that there is a difference between the EphMRA Guidelines and those of the BHBIA /ABPI in the UK</i></p>	<p>In all countries, unless otherwise directed by the client, the EphMRA Guidelines should be followed. The UK Guidelines should only be followed if directed to by the client. Following the EphMRA Guidelines, this means that in the event of an AE occurring that should be reported, physicians should be asked to get in touch with the client's Drug Safety department within 24 hours. A patient should be asked to speak to their physician within 24 hours.</p>
<p>5. <i>Is there a difference in the time that should be allowed to report an AE depending on how long the product has been available on the market?</i></p>	<p>Yes, pharmaco-vigilance personnel have indicated that if the product has been on the market up to three years then the pharma company has only 15 days to submit a report to the authorities. This means that a MR agency would need to provide the information to the pharma company very quickly, often in 24 to 48 hours of the AE being mentioned in a face to face or telephone interview. Some companies insist that it should be reported in 24 hours regardless. If the product has been available for longer than three years then the pharma company has to provide a quarterly report for such products and hence timing may not be so critical. It will be important for the MR agency to establish the company's policy, but they could ask for more time in the event of an older product being mentioned.</p>

<p>6. <i>Is there a difference between what might be regarded as a 'serious' AE and one that is not 'serious'?</i></p>	<p>Yes. However, a timeframe for reporting an AE should be given. The pharma company has defined rules on how quickly it needs to respond to a reported AE (e.g. 7 days for a life-threatening AE), and during that time the pharma company needs to assess the level of danger associated with that AE. The clock starts for this as soon as the AE is reported (i.e. by the patient or physician to, in this case, the MR interviewer). Therefore the interviewer needs guidance to report an AE immediately after an interview, it is not something to be put off until a later date. (Also see answer above) It should be within 24 hours.</p> <p>EphMRA's advice is that while differences do exist between what constitutes a serious and a less serious AE, it should be left to the Drug Safety/pharmaco-vigilance team to determine what is or is not a serious AE. Thus once such an issue that is linked to a clearly identifiable named patient occurs then the report should be sent within the timeframe outlined.</p>
<p>7. <i>When the interviewer reminds a doctor of his obligation to report an AE should this be recorded, so that there is a record of this happening?</i></p>	<p>Yes. This is good practice and is to be recommended as a safeguard for the agency.</p>
<p>8. <i>What happens if the study is online and the AE information is not discovered until the coding stage as no one sees the data until then?</i></p>	<p>It is obviously not possible to report on something that is not known about until it becomes available. However, once the information comes to light, then it should be treated in the same way as the points made in the previous question. It should be provided to the client within 24 hours of it becoming identified.</p>
<p>9. <i>If I am conducting a MR project for client A and an AE that is technically reportable occurs in an interview for a competitive drug, does that have to be reported to Company B?</i></p>	<p>No. It is not necessary to do this.</p> <p>Depending on the nature of the AE (i.e. if serious), you might consider mentioning it to the client company A and leave it to the Drug Safety department to consider whether to raise it with Company B or not.</p>

<p>10. If an MR agency is involved in conducting syndicated investigations and an AE that is reportable occurs, what does the MR agency do?</p>	<p>In those cases where a MR agency is conducting a syndicated investigation on its own initiative, and is offering the data to any potential pharma' company, as the MR agency is not under any legal obligation to provide details of AE's to the medical authorities no AE reporting is required. If special questions are asked for individual clients and these lead to an AE being mentioned, then the same guidance as mentioned above for custom MR applies. If more than one pharma company collectively request that a MR agency conduct a 'shared study' for them then the same rules for custom MR apply.</p> <p>With regard to any other audit undertaken by a MR company if the data collected is able to be purchased by any pharma company, then as the MR agency is not itself a pharma company it is not governed by any reporting rules to medical agencies involved in pharmacovigilance. Consequently it is not necessary to prepare any AE reports at this time.</p>
<p>11. Should we try to prepare questionnaires in such a way to try to reduce any likelihood of an AE occurring during the course of an interview?</p>	<p>No association can dictate what a MR agency or pharma MR executive should do in this regard. However, it is our view that great care should be taken when preparing a questionnaire so as not to bias any responses provided. If questionnaires are prepared in such a way that they try to avoid asking questions that might give rise to an AE, this might result in an unbalanced set of answers and not provide clients with appropriate 'balance' they would normally expect from MR investigations.</p>
<p>12. Do we have to ask Drug Safety personnel to approve MR questionnaires?</p>	<p>This may be dictated by the internal pharma company's own policy. However, such requirements would seem unnecessary and could result in significant timing issues for both pharma management team and the MR agency. It may be advisable to involve systematically DS for a given period of time to establish the link between MR and DS and make sure that both parties understand the issues. Based on this experience, we may not need to involve DS systematically after this period. It might be wise to establish what if any protocols exist prior to starting any study that could involve DS personnel to avoid cancellation fees and conflicts between MR client and MR agency executives. Drug Safety departments may wish to examine the questionnaire to see how much work might be generated for them from follow up calls about AE's, so this might slow down the timing and initiation of the study.</p>
<p>13. What, if any, precautions are needed if longitudinal patient MR is carried out?</p>	<p>If the study is one of audit information or syndicated and hence is not being conducted for a specific client on a customised basis, the same points apply to those cited earlier. However, customised studies of this type could lead to large volume of AE reports.</p>



*European Pharmaceutical Market Research Association*

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