EphMRA Code of Conduct 2018 – Log of Changes

New text is highlighted in yellow and deleted text is ~~crossed through~~

We have also flagged up in *italicised blue font* what type of change has been made.

1. Introduction

A. Purpose, Scope and Sources

EphMRA Members' Code Responsibilities *Extended guidance is provided*

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

2. Principles of the Code of Conduct

2.1 ***Edited Guidance***

VI. Data collection MUST be adequate, relevant and ~~not excessive~~ limited to the purpose (s) for which it is processed. Researchers MUST be transparent about the personal data they plan to collect, the reason(s) it is being collected and who it will be shared with.

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

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

3. Explanation of Key Principles

B. What Constitutes Market Research

Disguised Promotion

~~3.12~~ 3.11 *Edited guidance*

– There is no unnecessary use of company or brand names or over-emphasis upon claims or product messages, particular care should be taken if the names of unlicensed products are to be used

C. Data Protection and Privacy

Definition of Personal Data

~~3.16~~ 3.15 *Extended guidance given*

Personal data is any information relating to an identified or identifiable living person, who can be identified directly or indirectly by that data on its own or together with other data. Personal data, ~~or personally identifiable information(PII) as it sometime known~~, includes postal codes, cell phone numbers and email addresses as well as full names and postal addresses.
Sensitive or special category personal data is personal information which identifies a living individual and includes reference to: the racial or ethnic origin of the data subject; his/her political opinions; his/her religious beliefs or beliefs of a similar nature; whether he/ she is a member of a trade union; his/her physical or mental health or condition; his/her sexual life; the commission or alleged commission by him/her of an offence; or any proceedings for any offence committed or alleged to have been committed by his/her and the outcome. The definition of health data has been expanded to include biometric and genetic data. You must obtain explicit consent to process special category personal data. You must treat special category personal data with greater care than other personal data.

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

~~3.17~~ 3.16 *Edited Guidance*

Personal data ~~covered by the EU Data Protection Directive~~ includes data in a range of formats - ~~be it~~ alphabetical, numerical, graphical, photographical or acoustic. It includes information kept on paper, as well as information stored in a computer memory by means of binary code, or on a videotape, for instance. ~~In particular, sound and image data qualify as personal data from this point of view, insofar as they may represent information on an individual." (Article 29 DP working party opinion on the concept of personal data of 20 June 2007~~ Personal data includes video-streams (relayed live or delayed and non-anonymised recordings. Whether an audio recording is considered personal data may depend on whether the surnames of the individuals are recorded or whether the voice alone could lead to the identification of the individual.

~~3.18~~ 3.17 *Edited Guidance*

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

~~Definition of~~ Processing ~~of~~ Personal Data *Extended and updated guidance*

~~3.19 The processing of "*personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life*" is forbidden unless one or more of the exceptions specified in the Directive have been met. The most important of these exceptions, in the case of market research is where the MR subject has given his/her explicit consent to the processing of such data. Explicit consent refers~~

~~to a MR subject's specific and unambiguous agreement based upon adequate information (see Section 8, Informed Consent).~~

The 'processing' of personal data includes any operation or set of operations performed on personal data, including, but is not limited to: collecting, recording, organising, storing, adapting or altering, retrieving, consulting, using, disclosing by transmission, disseminating or otherwise making available, aligning or combining, blocking, erasing or destroying, whether automatically or otherwise. ~~the collection, recording, organisation, storage, alteration, retrieval, use, disclosure, dissemination, alignment or combination, blocking, erasure or destruction, of personal data.~~

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

Naming the End Client *Extended guidance is provided.*

3.19 There are three situations when the end client/commissioning client company must be named to meet GDPR requirements. These are as follows, if they:

- Are a data controller (see section 4H 4.19)

OR

- Are the source of personal data e.g. they supply a list of names to be used for sampling (see sections 4G, 4.10 and 4H 4.19)

OR

- Receive personal data e.g. they receive non-anonymised audio/video files – live or delayed (see section 5L 11.4)

These three situations all operate independently.

Security

~~3.22~~ 3.21 *Edited guidance*

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

~~3.23~~ 3.22 *Edited guidance*

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

Commission), impose broad overall security safeguards subject to enforcement within their jurisdiction.

Storing Agreements about Access to Personal Data *Edited guidance*

~~3.24~~ 3.23 *Edited guidance*

~~It is good practice for r~~ Researchers should ~~to~~ keep copies of e-mails and other documents received from MR subjects agreeing to, or restricting, the use of or access to their personal information. Unnecessary duplication of records should be avoided. ~~This is a legal requirement in some countries, amongst others, all European Union member states.~~

Protection of Personal Data when Transferred

~~3.25~~ 3.24 *Edited guidance*

Personal data is protected by the provisions of the ~~Data Protection Directive~~ GDPR even when taken out of the country where the MR subject lives. Personal data must not be transferred from one country to another without the consent of the individual or 'legally permissible grounds' for the transfer.

~~3.26~~ 3.25 *Edited guidance*

If personal data is to be transferred from one country to another, the data protection requirements of both countries MUST be met. The transfer of personal data to non-EEA countries is forbidden unless there is adequate privacy protection and specific data protection ~~contractual~~ arrangements in place.

MR subjects' Rights to Their Personal Data *Extended guidance is provided*

~~3.28~~ 3.27 *Edited guidance*

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

3.28 MR subjects MUST be made aware of their data protection rights ~~that they can ask at any time to know what personal data about them are currently being held and for these to be amended or destroyed~~ and the right to complain to a supervisory authority, their rights include to:

- ask what data is being held about them
- ask for the data to be amended or destroyed
- object to processing
- ask to move their personal data
- ask to restrict processing
- exercise their rights in relation to automated decision making and profiling.
- where the data processing is based and details of any data transfers to countries without adequate data protection

D. Market Research Tenets

Informed Consent *Extended guidance is provided*

3.3~~2~~ Consent must be a clear, unambiguous, affirmitive action. Consent should be 'purpose-specific' i.e. limited to one specific purpose.~~ESOMAR state that consent must be~~:

~~Free (voluntary and able to be withdrawn at any time);~~
~~Specific (relating to one or more identified purposes); and~~
~~Informed (in full awareness of all relevant consequences of giving consent).~~
~~http://www.esomar.org/uploads/public/knowledge-and-standards/codes-and-guidelines/ESOMAR-draft-Data-Protection-Checklist-September-2014.pdf~~

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

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

~~3.36~~ 3.35 *Edited guidance*

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

Confidentiality & Anonymity

~~3.39~~ 3.38 *Edited guidance*

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

Waiving Right to Confidentiality

~~3.41~~ 3.40 *Edited guidance*

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

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

In Germany MR industry guidelines prohibit transferring data that could identify MR subjects to the client. ~~Waive their anonymity/confidentiality~~.

4. Key Research Stages - Before Fieldwork

Extended guidance is provided

F. Data Protection

When preparing a proposal and considering the use of personal data within a MR project that falls within the scope of the GDPR a Data Protection Impact Assessment (DPIA) may be needed (or relying

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

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

H. ~~G.~~ Preparing the Sample

Drawing a Sample from a List *Extended guidance is provided*

4.7 However you MUST always have a lawful basis for processing personal data, whether the data is readily available in the public domain or not.

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

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

~~The original list holder MUST make sure that they have a legally permissible basis (generally either consent or legitimate interests)~~ The list holder should inform the supplier of the legal basis for passing on their list.

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

Revealing the Source of a List *Extended and edited guidance*

4.10 When lists of named individuals are used for sample selection, the source of the list should be revealed to potential MR subjects. Under GDPR, the source of the list MUST be named. ~~The source of the list MUST be revealed to potential MR subject(s) at an appropriate point in the interview, if it is requested. In Germany MR industry guidelines state that MR subjects MUST be told the client company's identity if the client company supplied their name.~~ If providing the name of source of the personal data would impact the integrity of the MR it may be withheld until the end of the interview but respondents must be made aware at recruitment that:

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

The justification for this should be documented.

~~4.10 This can be given at the end of the interview rather than the beginning, but it MUST be given.~~ ~~**In Finland, a** researcher MUST NOT disclose the identity of the sponsor (unless legally required to do so) to any third party without the consent of the sponsor)~~

Correcting Listed Information Edited guidance

4.11 You have a responsibility to make sure that any personal data you process is accurate and up to date. Reasonable steps must be taken to correct or erase inaccurate data promptly. ~~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 alloweable to pass back the personal details of those who have:~~

~~4.12 Died or moved away – so they may be removed from the list~~
~~4.13 Asked that their details should be marked 'do not contact' or removed from the list~~
~~4.14 Agreed to be re-contacted for specific follow up~~
~~4.15~~ ~~4.11~~

Adding Personal Data to a Database

~~4.16~~ 4.12 Edited guidance

Personal data can be added to the database only if you have a lawful basis for this e.g. the MR subject is told of this intention at the time of data collection ~~except **in Germany**~~. MR subjects MUST also be told why and for what purposes the data will be used, and that under no circumstances will it be released or used for any non-research purpose.

I. H. Recruitment

Recruitment – Information that MUST be Communicated *New Guidance*

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

EFPIA members and members of EFPIA-affiliated associations MUST document an agreement between agency or client company and the healthcare professional MR subject in advance of fieldwork (i.e. at recruitment) for all market research carried out face to face. Longitudinal studies and panels MUST also be covered by a written agreement irrespective of methodology. Single stage market research studies conducted online, by telephone or by post that involve only minimal remuneration do not require a written agreement in advance of fieldwork. EFPIA member associations provide guidance on the meaning of minimal. This ruling is based upon Article 14 of the European Federation of Pharmaceutical Industries and Associations (EFPIA) *Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals.*

http://transparency.efpia.eu/uploads/Modules/Documents/efpia-hcp-code-2014.pdf

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

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

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

In the **UK** the BHBIA states that to conform to Clause 20 of the ABPI's Code of Practise 2016, all study types irrespective of methodology require a written agreement; although different

mechanisms to capture the agreement may be needed for different methodologies. For full details see the BHBIA Guidelines.

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

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

- Subject and purpose of the MR
- Methodology and approach
- Location and duration of fieldwork
- Date and time of fieldwork
- Reimbursement offered – both the nature and the rate of remuneration
- Adverse event and product complaint reporting obligations if appropriate

- Templates for a standard text are available in **Germany** (http://www.akdae.de/Arzneimittelsicherheit/UAW-Meldung/index.html and http://www.akdae.de/Arzneimittelsicherheit/UAW-Meldung/UAW-Berichtsbogen.pdf) and the **UK** (http://www.bhbia.org.uk/guidelines/abpiadverseeventguidelines.aspx). Furthermore **in the UK** non-healthcare professionals MUST be informed that if adverse events are discussed during the research, then the details will be collected and forwarded to the commissioning pharmaceutical company.
- In **Mexico**, the privacy disclaimer (aviso de privacidad) has to be provided (in writing or read) to the MR subject, or a source for it given (i.e. hyperlink). MR subjects must consent to the terms of the privacy disclaimer.

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

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

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

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

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

Naming the data controller, source and recipients of personal data

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

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

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

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

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

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

Data Collected at Recruitment

~~4.25~~ 4.21 *Edited guidance*

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

~~Recruitment Agreements and~~ Disclosure *No longer needed*

4.27 ~~EFPIA members and members of EFPIA-affiliated associations MUST document an agreement between agency or client company and the healthcare professional MR subject in advance of fieldwork (i.e. at recruitment) for all market research carried out face to face. Longitudinal studies and panels MUST also be covered by a written agreement irrespective of methodology. Single stage market research studies conducted online, by telephone or by post that involve only minimal remuneration do not require a written agreement in advance of fieldwork. EFPIA member associations provide guidance on the meaning of minimal. This ruling is based upon Article 14 of the European Federation of Pharmaceutical Industries and Associations (EFPIA)~~ ~~*Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals.*~~
~~http://transparency.efpia.eu/uploads/Modules/Documents/efpia-hcp-code-2014.pdf~~

~~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 (as well as primary market research records containing personal data) and MUST be destroyed when the purpose of the market research study is redundant.~~

~~In **Denmark**, nurses must be treated as non-HCPs.~~
~~In **Germany** the FSA requires that if the incentive is not 'marginal' (which is defined as over 50 euros) written contracts are required for all forms of market research with HCPs.~~

~~In the **UK** the BHBIA states that to conform to Clause 20 of the ABPI's Code of Practise 2014, all study types irrespective of methodology require a written agreement; although different mechanisms to capture the agreement may be needed for different methodologies. For full details see the BHBIA Guidelines.~~

~~http://www.bhbia.org.uk/guidelines/legalandethicalguidelines.aspx~~

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

~~Disclosure Requirements~~

Consent and record keeping required *Extended guidance*

~~4.48.114~~ 23.11

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

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

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

Re-contacting MR subjects *Extended and edited guidance*

~~4.27 Informed consent requires that if it is necessary to contact a MR subject again to ask further questions (other than for quality control purposes), consent for re-contact MUST be sought at the time of the recruitment interview or during the interview; even if only simple clarification is needed~~. ~~When children are researched consent for re-contact should be sought from the responsible adult and the child separate~~ Under GDPR, you can only re-contact respondents if they have a lawful basis e.g. consent for this. So, if you think you might wish to contact a respondent again (even if only for simple clarification), you MUST obtain their consent before the end of the interview. When children are researched consent for re-contact should be sought from the responsible adult and the child separately.

~~4.32~~ You don't need to obtain their consent before re-contacting them for MR quality control purposes or data validation, these would be very likely to be in the data's controller's legitimate interests but this must be subject to assessment. If you know you'll definitely need to re-contact respondents for a second stage or follow-up research, you must make this clear and get consent for this, at recruitment

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

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

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

J. ~~I.~~ Incentives

Confidentiality of Recipients' Incentive Data

~~4.69~~ 4.44 *Extended guidance*

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

5. Key Research Stages – During Fieldwork

K. ~~J.~~ Information to be Communicated at the Start of Fieldwork

Edited guidance

5.1 Before fieldwork starts all of the information detailed in section 4.20 MUST be communicated to respondents. ~~The following information should be provided to MR subjects at the start of fieldwork, even though much of this information will have been communicated at recruitment:~~

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

L. ~~K.~~ Instrument and Stimulus Design and Use

Stimulus Material *Extended guidance*

~~8.5~~ 8.6 Companies may want to consider the need for respondents to sign some form of confidentiality or non-disclosure agreement if commercially sensitive information is shared with them and the respondent is made aware of the identity of the end client company

M. ~~L.~~ Recording and Observation of Fieldwork

Personal Data Definition *Extended guidance*

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

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

Consents Required

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

Information to be Communicated to MR subjects when Observed by Client

11.4 When the end commissioning client is viewing non-anonymised fieldwork live or at a later date via streaming or video-relay ~~If recordings (to be viewed live or later) of non anonymised fieldwork are to be made available to the commissioning client company~~, this is a transfer of personal data, consequently in order to meet the requirements of informed consent, MR subjects ~~should~~ MUST be told:

- The name of the recipient company
- If naming the recipient company is likely to impact on the integrity of the MR ~~MR subjects agree~~ the company name can be withheld until the end of the interview ~~fieldwork~~ if MR subjects agree ~~to avoid bias or the threat of disguised promotion~~ . However if MR subjects do not want their non-anonymised input to be viewed this MUST be respected.
- Why they are viewing – different purposes require separate consents
- Who (in terms of role/position not names) will see/listen to it

- Of the countries outside their own to which non-anonymised information will be transferred or viewed e.g. inform MR subjects filmed in France that the film will be viewed in the USA.
- Of their right to withdraw consent
- How and who to contact within the MR agency with any questions or concerns.

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

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

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

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

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

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

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

When Written Consent is Required

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

When a MR Subject Withdraws

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

~~**When Recipients of Recordings Change**~~ *No longer required*

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

Listening In or Audio-only recordings

~~11.10~~ 11.9 *Edited guidance*

If it is possible that the MR subject could be identified by the audio-recording alone they should not be passed to client companies unless there is a lawful basis in place e.g. the MR subject has given their informed consent**.** **In Germany** transferring information that could lead to the identification of the MR subject to the client is, ~~although requesting consent is~~ prohibited by MR industry guidelines ~~**in Germany**~~. Listening in to audio only recordings of a simultaneous translation (without the MR subjects' voice) would be anonymous assuming no personal data was revealed, it is always the data controller's responsibility to make sure that anonymity is not compromised.

Client Awareness of Restrictions on use of Recorded Data

~~11.11~~ 11.10 *Edited guidance*

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

EphMRA Adverse Event Reporting Guidelines ~~2015~~

Passing on Reporter Contact Details	Whenever possible, contact details for the reporter should be recorded so that follow-up activities can be performed. However, if the reporter does not wish to provide contact details, the ICSR should still be considered as valid providing the organisation who was	Researchers must ask the reporter if they are willing to provide their contact details and allow these to be passed to the MAH so that if required PV follow up is possible. Contact details (i.e. personal data) cannot be passed on without consent, explicit consent in the case of patients.

	informed of the case was able to confirm it directly with the reporter.	When securing consent to transfer personal data to the pharmaceutical company for AE reporting the GDPR requires that the recipient company is identified. As AE reporting is a separate processing operation (to the MR), consent for this may be secured at the end of the interview. In addition, when asking for consent to pass on contact details, it must be clear that the MAH can only use the personal data for AE investigation purposes and reporters must be made aware that they may be re-contacted with regard to the AE by the MAH. AEs can be forwarded without contact details if consent to pass these on is denied. In Germany MR industry guidelines prohibit revealing MR subject identity to the client. It may be practical to request that the MR agency facilitates any follow up between the MAH's PV department and the reporter (so protecting the reporter's anonymity) by allowing questions and answers to be passed via the agency with no personal data passed to the MAH.

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

6. Key Research Stages – After Fieldwork

O. Analysis and Quality Control

13.1 Researchers and agencies should anonymise or pseudonymise personal data as soon as possible during the MR process.

P. ~~O~~. Storage and Security

Storage Duration

~~13.3~~ 13.4 *Edited guidance*

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

Security *New guidance*

13.6 All those processing personal data should have a data breach notification policy in place. For more information on data breaches please see the EphMRA guide 'GDPR Data Security' available to members on the EphMRA website.

Q. Reporting Market Research

~~13.8~~ 13.11 *New guidance*

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

7. Researchers' Responsibilities by Research Approach

Edited guidance

S. Face to Face Methodology

14.1 ~~The name of the agency for which the interviewer is working (whether employed or sub-contracted) should be given verbally and it~~ It is good practice for the interviewer to provide an identity card ~~give his/her name~~ to the MR subject.

T. ~~S.~~ Telephone Methodology

Naming the Agency/Researcher

~~To gain the trust of the MR subjects without having the benefit of face to face contact, t~~ The interviewer MUST ~~should~~ give the name of the agency that he/she represents and MUST give their own or an agreed contact name.

~~**MR Subject Costs**~~ *No longer required*

~~15.1 If using a mobile phone means the MR subject incurs a cost this should be reimbursed, researchers should ensure that participating in market research does not disadvantage MR subjects financially.~~

Use of Apps

~~15.6~~ 15.5

You must have a lawful basis e.g. MR subject consent ~~is required~~ for the use of an app and MR subjects MUST be made aware of its purpose, the type of data it collects and its impact on functioning or performance such as degradation of battery life. See also 17.7 and for further details see ESOMAR's Guideline for Conducting Mobile Market Research.

V. ~~U.~~ Online & Mobile Market Research

Informed Consent *Edited guidance*

17.5 If relying on informed consent you must provide an easy way for MR subjects to supply and withdraw it ~~and a means to provide it are required. Written consent is preferable but use of an on-screen check box is generally acceptable for data protection purposes.~~

Privacy and Data Protection *Edited guidance*

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

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

17.9 If a repeat or follow-up survey is intended, a lawful basis for storage of their contact data e.g. consent is needed.~~statement concerning Data Protection MUST be displayed on the MR subjects' 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. MR subjects should also be given the opportunity to print out this statement.~~ The MR subjects MUST be able to refuse further participation in the survey via a suitable option and to refuse further contact by email in connection with the survey.

MR Subject Costs

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

Protecting Personal and Company Data

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

Cookies *Edited guidance*

~~17.15~~ – 17.14

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

Identification of the Client *Extended guidance is provided*

~~17.19~~ 17.18

Data protection law requires you to identify data controller(s), recipients of personal data and the source of the personal data (if it wasn't obtained directly from the individual). Therefore the end client company needs to be identified if they any one of these three criteria. ~~Studies should provide either the client's identity or an opportunity to ask for it if there is no interviewer to make the request of spontaneously, at an appropriate point within the study - the client's identity should be given if sampling from a customer database (i.e. the client supplied a list of potential MR subjects).~~

Using Identification and Tracking Technologies/Software

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

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

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

Online Access Panels

~~17.24~~ 17.23 *Edited guidance*

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

W. Social Media

Passive market research i.e. digital listening, scraping *Edited guidance*

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

18.6 Quotations containing personal data~~ly identifiable information(PH)~~ can only be provided to the client if you have a lawful basis for this e.g. the contributor has given their consent for this and it has been made clear that they will not be subject to promotion as a result of this**. In Germany**, MR subject identity must remain anonymous and MR subjects cannot be asked to waive their right to confidentiality

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

Active market research i.e. engaging with participants

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

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

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

8. MR Subjects' Rights by MR Subject Type

X. ~~W.~~ Patients

New guidance is provided

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

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

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

Y. ~~X.~~ Simulated Consultations

AA. Children and Young People

Definitions *New guidance is provided*

21.1 If you are relying on consent as your lawful basis for processing personal data, when offering online services directly to a child, only children aged 13 or over are able provide their own consent.

Consents Required

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

Sources

Amended guidance

Legislation Supporting The Code of Conduct

- ~~EU Data Protection Directive 1995~~
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

UK

- Data Protection & Research: Guidance for MRS Members and Company Partners 2018
- ~~Protection Act 1998 & Market Research: Guidance for MRS Members 2003~~

Appendices

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

Pro Forma 1 – Recruitment Agreement	
Recruitment Agreement **TO BE USED IN CONJUNCTION WITH A RECRUITMENT SCRIPT THAT DETAILS THE MR TERMS**	
Project Title:	Project No:
Nature of Project	
Subject and purpose of market research study:	
Methodology and Approach	
Fieldwork	
Location: (If online or telephone, please state this)	Duration:
Date:	Start Time:
Incentive	
Type: (e.g. cash)	Amount:
MR Subject Agreement and Signature	
By signing below/clicking on the box below/returning this email (AMEND AS APPROPRIATE) I consent to <agency name> collecting and using the information about me that I voluntarily provide for the purposes of market research YES NO I have read, understand and agree to the terms described. YES NO OTHER CONSENTS MAY NEED TO BE ADDED	
Signature:	Name (please print)
MR Subject Code Number	
Code Number	

Pro Forma 3 – MR Subject Consent Allowing Client Access to Recordings

MR Subject Consent Allowing Client Access
To ~~Recordings of~~ Market Research Fieldwork

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

Declaration

I understand that the company that commissioned this market research study

_____

(name of recipient organisation(s) may or may not be required will:
DELETE AS APPROPRIATE

- Watch through a one way mirror (watching organisations do not need to be named) but type of organisation(s) should be specified
- Listen to an audio recording at their offices (organisations listening in may or may not need to be named depending on whether audio information is considered personal data or not)
- Watch a video recording at their offices (watching organisation(s) must be named but naming may be delayed until the end of the interview if viewing is not live)

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

_____

_____

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

_____

_____

I understand that all those listening, watching or viewing the recording MUST respect the confidentiality of all information exchanged in market research interviews/groups and that no sales approaches will ever be made to me as a consequence of the company having this access.

I understand that I can withdraw my consent at any stage.

IF APPROPRIATE We would prefer not to reveal the name of the healthcare/pharmaceutical company until the end of the interview, just in case knowing this affects any responses. Is this acceptable to you or not? YES NO

Signatures

I have read, understand and agree to the terms above.

MR Subject Signature:	Name (please print)
Agency Signature:	Name (please print)

MR Subject Code Number

Code Number

Pro Forma 4 – Client Agreement to Safeguard Confidentiality of Recordings

Client Agreement to Safeguard Confidentiality of Recordings of Market Research Fieldwork

Project Details	
Project Title:	Project No:
Agency:	Location(s) of Fieldwork:
Date(s) of Fieldwork:	Start Time(s) of Fieldwork:
Commissioning Client Company	

Declaration

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

_____

_____

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

_____

_____

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

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

- Those listening to or viewing the recording will respect the confidentiality of all information exchanged in market research interviews/groups
- No sales approaches will ever be made to MR subjects as a consequence of having this access.
- No attempt will be made to reverse any anonymisation
- The recording will be stored securely, kept separate and processed in accordance with applicable data protection/privacy laws and market research professional codes
- The recordings will be destroyed or handed back to the agency as soon as is required.
- If video streaming has been used to allow remote viewing it is possible that the video transmission system used delivered a copy of the recording to the receiving computer. If this is the case any copy of the video stream saved on the observer's computer MUST be deleted.

Signatures

I have read, understand and agree to the terms above

Company Signature:	Name (please print)
Agency Signature:	Name (please print)

Pro Forma 5 – Observer Agreement

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