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Legal and Ethical Guidelines
for Healthcare Market Research

Your essential guide

July 2018

Welcome to your guide to the legal and ethical requirements of carrying out market research in the UK healthcare market.

We've been supporting the UK market research community since 2005 with our Legal and Ethical Guidelines for Healthcare Market Research – to help us all reduce risk, improve performance and make life a little simpler by drawing key information together in one place. And it's good to know The Association of the British Pharmaceutical Industry (ABPI) refer their members to these guidelines too.

Of course, we review our guidelines regularly, keeping them up to date with the impact of any relevant legislation or other industry guidelines. This July 2018 update incorporates the impact of new data protection requirements introduced via the General Data Protection Regulation (GDPR) and the UK Data Protection Act (DPA) 2018. Please see page 4 for a list of the key changes made.

This document is provided by the BHBIA for information purposes only and is not intended and should not be construed as regulatory or legal advice. This guide does not cover all legislative and regulatory requirements pertaining to Members and it is the responsibility of all Members to familiarise themselves with these.

We hope you'll find them helpful and easy to use.

The Guidelines are maintained by the BHBIA's Ethics & Compliance Committee, within which the Guidelines team is dedicated to providing clear guidance to all those involved in healthcare market research.

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British Healthcare Business Intelligence Association

If you have any queries about these Guidelines, or any legal or ethical questions about UK healthcare market research that aren't answered here, please visit www.bhbia.org.uk and submit your query via Guidelines > Request Advice.
(Note: this ad hoc advisory service is available to full BHBIA members only).

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GDPR UPDATED LEGAL & ETHICAL GUIDELINES

– KEY CHANGES

Key changes have been made in the following areas and are highlighted throughout the Guidelines.

- **Guiding principles** *Section D*
 - Updated but not significantly changed
- **Writing a proposal** *Section E2.3*
 - Drawn attention to need for data protection impact assessments
- **Recruitment agreement and securing consent** *Section E4.2*
 - Updated the information that must be delivered to secure informed consent
 - Added information about the requirement to name data controller(s), the source of and the recipients of personal data
- **Recruiting from a list or database** *Section E4.4*
 - Stressed the requirement for an appropriate legal basis for data processing and the need to name the source of the personal data (if it's not the data subject)
 - Updated the requirements when correcting, adding to and erasing personal data
- **Handling data** *Section E4.5*
 - Added new safeguards needed when transferring personal data
- **Data minimisation** *Section E5.1*
 - Stressed the need to minimise the amount of personal data collected
- **Use of confidentiality agreements** *Section E5.4*
 - Added advice suggesting the use of confidentiality agreements when certain types of information are revealed during market research as well as the end client's identity
- **Observing and recording** *Section E6.3*
 - Detailed important changes to data protection requirements when transferring recordings of non-anonymised fieldwork
- **Storing and accessing respondent data** *Section E7.1*
 - Added prompts on data minimisation, breach notification and respondents'/data subjects' rights
- **Children and young people** *Section F3*
 - Added the age of consent for processing personal data when supplying online information services to a child
- **Follow-up studies of representatives' visits** *Section G8*
 - Added the requirement to name the source of the contact list (if one is used)
- **Definitions** *Section H*
 - Updated 'personal data', 'data processing', 'informed consent' and 'explicit consent'
- **Data protection legislation** *Section I*
 - Updated
- **Key terminology** *Section K*
 - New and updated terms added including 'anonymised data', 'explicit consent', 'personal data', 'profiling' and 'pseudonymisation'
- **Sources** *Section L*
 - Updated sources
- **Pro formas** *Section M*
 - Updated pro formas 1, 2, 3, 6, 7 and 8

A WHO'S THIS FOR?



You

- If you're involved in any pharmaceutical or healthcare market research (MR), business intelligence or customer insight or consultancy.
- If you're working in or for a BHBA member company

Whether you specialise in commissioning, conducting, observing or communicating MR, our guidelines will keep you on the straight and narrow – supporting and protecting you and the people you work with.

The guidelines apply to all methodologies, project types and mediums too – qualitative, quantitative, customer satisfaction, user experience or co-creation work carried out face to face, by telephone or online.

And remember, if you work in a BHBA member company, you must follow these guidelines. It's an important condition of your membership. The same goes for the joint [ABPI/BHBA Guidance Notes on the Collection of Adverse Events and Product Complaints from Market Research Programmes](#). (We refer to these now and then in this guide.)

When we refer to 'you' within the Guidelines, we mean BHBA members.

And your connections

We recommend that you include a clause in contracts and Master Service Agreements that commits everyone involved in a MR study (i.e. the commissioning company, the MR agency and any subcontractors) to following these guidelines.

If you work in a BHBA member company, you must make sure that all relevant colleagues, clients, contractors and subcontractors are familiar enough with these guidelines to be able to satisfy them, and that their working arrangements comply with them.

B HOW WILL IT HELP?



You have the key information you need in one place to make sure your MR project goes smoothly from a legal and ethical point of view. We've laid out the information in project order so it's easy to follow and refer back to. By using this guide, you can minimise the chance of things going wrong, which wastes time and could even lead to prosecution. And you can gain in positive ways too.



- Avoid breaking the law
- Avoid ethical errors
- Avoid damaging your professional reputation



- Find information quickly, saving time and money
- Impress colleagues with your knowledge and expertise
- Create consistency across your projects

C GET FAMILIAR IN FIVE MINUTES



Don't be put off by the size of this guide – it's full of valuable information you may need to look up in the future. But it's more than a reference document, especially if you're relatively new to MR or to the BHBA. So here are three simple steps to help you start getting familiar fast.

1. Know what you must and mustn't do! We make a distinction between actions that we advise you to take and those that are compulsory. When we're advising, we say *should*. When it's compulsory, we say *must*. **And we highlight everything you really must do in bold like this.**

2. If you do nothing else today, read our twelve simple guiding principles (section D).
3. If you get involved in most stages of a MR study, skim through the headings and subheadings of section E Get it right every stage of the way.

We also recommend that you familiarise yourself with the key words and phrases set out in section H, Some important definitions and section K Key Terminology. This Guide is based on the legislation and codes listed in section S Sources, and we recommend that you familiarise yourself with that section.

D FOLLOW OUR SIMPLE GUIDING PRINCIPLES



Twelve basic principles underpin our guidelines. These represent the essence of what we consider essential and right for everyone working in healthcare market research. The first four are fundamental.

1. You must obtain **informed consent** from MR respondents, willingly given, to collect and use their data. Before you do this, you must make sure they clearly understand the specified and lawful purposes for which you're collecting the data and how it will be used. In cases where you are collecting and using special category personal data, you must obtain explicit consent. **Special category personal data was formerly referred to as sensitive personal data and includes information about a person's health.**
 2. You must always observe the **rights of respondents**, including those of confidentiality, anonymity, and the right to withdraw at any stage.
 3. You must keep MR separate from any form of **promotion**. You must never use MR as a vehicle for disguised promotion.
 4. You must forward any **adverse events** raised during the study (that meet the criteria) so you fulfil your responsibility to drug safety. You must of course do this without compromising respondents' rights to anonymity and confidentiality.
5. You must ensure data collection is adequate, relevant and limited to the purpose(s) for which it is processed.
 6. You must treat respondents with respect. You must take all reasonable steps to ensure you do not harm or disadvantage respondents as a result of your professional activities.
 7. You must ensure that data is processed fairly, lawfully **and transparently**. And that you only use it for the specific, explicit and legitimate purposes that you originally obtained it. You must ensure that personal data is accurate and kept up to date. You must ensure that personal data is processed in accordance with the rights of individuals under the Data Protection Act 2018.
 8. You must take appropriate technical and organisational measures to **keep data safe and** prevent unauthorised or unlawful processing. You must protect personal data from being accidentally lost, destroyed or damaged.
 9. You must only transfer data (to a third party or overseas) if it is adequately protected.
 10. You mustn't keep data longer than needed to fulfil the purpose for which it was collected.
 11. You must behave ethically. You mustn't undermine or damage the reputation of pharmaceutical MR in the UK.
 12. You must conduct MR accurately, transparently and objectively.

You must conduct MR in accordance with relevant national and international legislation, including in particular the Data Protection Act 2018.

E GET IT RIGHT EVERY STAGE OF THE WAY



Our detailed guidelines now follow the eight stages of a MR project. Where we say *client* or *company*, we're referring to the commissioning pharmaceutical company. *Agency* refers to the MR agency contracted to conduct the study for the client.



1 Requesting a proposal

1.1 Objectives

When you send out a request for a proposal (RFP), you must have a genuine reason for carrying out market research to achieve your objective.

1.2 Seeking proposals

You should provide the same information to all competing agencies and tell them how many agencies are submitting proposals.

You mustn't show an agency's proposal to a third party (such as another agency or a researcher), unless the agency agrees first.

And no-one should use an agency's proposal to influence the proposals of other agencies or researchers.



1.3 Proof of competency

You should ask agencies how they would provide proof of competency and compliance. We suggest you include this in any contract or Master Services Agreement you have in place. We can help any agencies to meet your requirements as we offer training and certification of competence for both our BHBIA Legal and Ethical Guidelines and our Adverse Event Reporting Guidelines.

2 Writing a proposal

2.1 Content

You must ensure your proposals clearly communicate whether:

- you will combine or syndicate the work in any way
- you will use subcontractors or other third parties and what work they will do.

You should tell clients who the subcontractor or third party is, if they ask



2.2 Conflicts of interest

You should avoid any conflicts of interest. Provide everyone concerned with full details of everything that might be considered a conflict as early as possible. If you're concerned that your involvement with a product or company will compromise your input to a competing product or company (e.g. because you also work with their competitor), raise this up front, and ideally before you submit the proposal.

You should also clearly explain how you will handle any potential conflict e.g. separate project teams, agreement with confidentiality contracts etc.

2.3 Data protection

When preparing a proposal and considering the use of personal data within a MR project a Data Protection Impact Assessment (DPIA) may be needed (or relying on one previously carried out 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.bhbja.org.uk/guidelines/gdprupdates.asp>

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

3 Sampling

3.1 Respondent types

They must be relevant to your study objectives.

See Section F Respondent types for further guidance.

3.2 Sample size

You must limit this to only what's necessary for the MR objectives.

It should also be appropriate to type of market research.

There are no fixed guidelines on sample size. It's affected by the objectives, universe size, analysis requirements and the level of statistical confidence needed.

Beware of a disproportionately large sample size – your MR may be misconstrued as disguised promotion. See ABPI Code of Practice, Clause 12.2.



4 Recruiting and reimbursing

4.1 Key recruitment principles



What you must do for respondents:

- Ensure they're taking part in MR voluntarily, by providing enough clear and relevant information to help them decide what they want to do
- Invite them all to take part in the MR in a consistent way
- Inform them about the research study in the clearest and least confusing way
- Tell them exactly what participating will involve
- Let them know they can withdraw at any time
- Ensure they know what will happen to their data and how it will be used
- Keep their identity anonymous from the client unless they give permission for it to be revealed
- Make it clear that all the personal data collected during the project will be kept secure
- Ensure that no information identifying them (e.g. in recruitment questionnaires, reimbursement and attendance lists, or primary data) goes to the client without their consent for this

Remember, you must **never** mislead respondents into agreeing to take part.

The BHBA has provided a generic 'recruitment script' to encourage a simple, concise and consistent approach to recruitment – see section M Pro Forma 1. It will need to be tailored to the project and the medium (face to face, telephone, online).

- Non-research projects

If you're doing market research alongside a non-research activity, you must get the respondents' consent for the non-research activity when you recruit them. You should separate and clearly distinguish market research from any other activity.

When approaching anyone for non-research purposes, you mustn't confuse or mislead them, or make them believe you're asking them to take part in a MR project.

- Over-recruitment of respondents

If you recruit more respondents than are needed for fieldwork (to counter-act 'no shows'), you must treat those that are not needed with care and respect. If possible, they should be included in the fieldwork, if this is not possible they must receive the agreed incentive. If over recruitment is planned, you must tell respondents this at recruitment, they must understand that they may not be needed but will be given the full incentive if this is the case.

- Over-research of respondents

You should never do this. Your recruitment screeners should specify that respondents should not have taken part in similar MR in the recent past. You need to consider the individual respondent and study type when deciding what 'the 'recent past' is.

- Confidentiality waivers

Respondents may waive their right to confidentiality if you ask them to and they consent to this. You need to give them the following information to help them decide whether they want to do this:

- Who will see their data or be aware that they have taken part in the MR
- What will happen to the information they give. If it will be used for more than one purpose, you must make this clear
- What, if anything, will happen to them as a result of this waiver

You must record the consent (in writing or via an active opt-in check-box online).

4.2 The recruitment agreement and securing consent

If personal data are to be obtained directly from an individual e.g. via a MR interview, the information below must be delivered when it's obtained i.e. at recruitment.

If the personal data are not obtained directly from the individual e.g. it came from a customer database, the information overleaf must be delivered:

- when the first communication takes place If the data are to be used to communicate with an individual
- if the data are to be shared/disclosed before this happens.

- Obtaining agreement

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.

BHBIA, MRS and ABPI requirements mean the agreement/consent must include:

- subject and purpose of the MR study
- 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

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

- identity and contact details of the data controller(s)
- agency or researcher name and contact details – name, telephone number, email address as appropriate
- source of their personal data if it didn't come from the data subject, this may require you to name another organisation eg 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 eg 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

See section M Pro Forma 2 for a template for this.

- 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.

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

- Agreement mechanisms

- **Consent must be a clear, unambiguous, affirmative action**
- Online – respondents can agree by clicking on an acceptance box. A signature isn't required
- Telephone – respondents can agree verbally but ABPI requirements mean that they must then follow up by email, post or fax.
- Recruitment to a panel – respondents must agree to an 'up-front' contract for ongoing participation in MR studies. This must describe the nature of the MR, how the respondent will be remunerated and at what rate. You can obtain 'one-off' agreements from panellists, rather than for each survey (as long as they receive all the required information up front too)

- Parties involved

The agreement must be between two named parties, generally the individual respondent and the agency. However, if the agency sub-contracts recruitment, as long as the recruiter is under contract to the agency, the recruiter may be a named party, and can send out and store the agreement. The recruiter will then be a 'data processor' and there must be an appropriate 'data processing' agreement in place between the agency and the recruiter.

- Keeping records

You must keep records of the consent agreement along with other project data and fieldwork materials until the purpose(s) for which you collected them (and for which you must have consent) are redundant. Your records should include who consented, when, what they were told, how they consented and if appropriate if they withdrew consent.

- Specific consent

Consent must be specific to a single purpose. Different purposes and different data processing activities require separate consents. eg consent to store individuals' personal data on a database, consent to video record their participation in a group discussion for analysis, consent to share this with the commissioning client.

For further details see:

The BHBIA's GDPR guides available on the BHBIA website:

- [GDPR – Legal grounds for Data Processing](#)
- [Consents for Market Research What is required and when](#)

<https://www.bhbia.org.uk/guidelines/gdprupdates.aspx>

<http://www.pmcpa.org.uk/thecode/Documents/Code%20of%20Practice%202016%20.pdf>

4.3 Disclosure requirements

- When disclosure is required

The ABPI's disclosure requirements apply to BHBIA member companies who are also ABPI members or non-members who have agreed to adhere to the ABPI Code.

Disclosure requires pharmaceutical companies to make publicly available the details of MR-related payments (incentives and/or expenses), on a named basis, if the identities of HCPs or healthcare organisations ("HCOs") who take part in the MR are known or disclosed to the pharmaceutical company.

Within the ABPI Code these payments are called 'Transfers of Value'. The term 'transfer of value' means a direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional

purposes or otherwise, in connection with the development or sale of medicines. Indirect transfers of value include those paid to an employer, healthcare organisation or to companies or charities.

This disclosure requirement applies whether the HCPs/HCOs are paid directly or indirectly via an agency, recruiter or interviewer, where the identity of the company making the transfer of value is known to or can be identified by the recipient. It also applies to prescription bound medicines and to non-prescription bound medicines if they are dispensed on prescription.

The ABPI defines:

- HCPs as any member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of their professional activities, may administer, prescribe, purchase, recommend or supply a medicine.

Essentially the definition of HCP also includes: officials or employees of government agencies or private or public sector organisations that may administer, prescribe, purchase, recommend or supply medicinal products. The ABPI refer to 'other relevant decision makers' as particularly including those with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not health professionals.

- HCOs include a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more health professionals or other relevant decision makers provide services. If a healthcare organisation consists of only one health professional or other relevant decision maker then it would be subject to the requirements in the Code regarding individual health professionals. Patient organisations are not included within this definition.

- How does Data Protection law affect disclosure

If a HCP refuses to allow use of their personal data for disclosure and so can't be named for legal reasons, MR payments reported will be aggregated (with other HCPs who wish to remain anonymous) and the HCP can still participate in the MR.

- When disclosure is not required

If the HCP's/HCO's identity is not known to the commissioning pharmaceutical company disclosure is not required.

The PMCPA have informally advised us that if there was never an intention to identify HCPs to the pharmaceutical company but an HCP respondent becomes known to the pharmaceutical company as a result of another process e.g. AE reporting, then disclosure is not likely to be required. The 'other process' being an indirect consequence of the MR rather than a direct outcome.

This means that disclosure may not be required if:

- an adverse event is forwarded and it contains HCP reporter details – EFPIA have confirmed this within their FAQs
- or
- when viewing fieldwork a pharmaceutical company observer happens to recognise and can identify what should have been an unknown HCP respondent

For the full text of the PMCPA's advice please see the 'Update on the Implementation of the ABPI Disclosure Requirements' on the BHBIA website: <http://www.bhbia.org.uk/latestnews/news/abpidisclosure.aspx>

If you are unsure whether disclosure is required or not, the commissioning pharmaceutical company should be consulted or the PMCPA. Generally speaking if in doubt, disclose the transfer of value.

If the commissioning pharmaceutical company provides a list of potential HCP/HCO respondents for interview, unless everyone listed is interviewed (a census), the identity of those actually interviewed won't be known and so disclosure may not be required.

- What must be disclosed

The information that must be disclosed includes the total amount paid in a calendar year to each HCP/HCO by name.

The ABPI has developed a template showing exactly what data must be provided, this includes:

For individual named HCPs (that have given their consent for their personal data to be used in this way) or HCOs:

- Name including title, first name, initial*, last name (HCP only)
 - Speciality* and role* (HCP only)
 - City, country and address of principal practice (HCP only)
 - Institution name, location*, address lines 1, address line 2*, post code, email address**
 - Local register ID or third party database ID
 - Fee for service and consultancy i.e. the market research incentive
 - Related expenses
- *denotes optional information
**denotes to facilitate process not published on database

Aggregated information – where information cannot be disclosed on an individual basis for legal reasons, i.e. when a HCP refuses consent for the use of their personal data for disclosure, the following must be provided:

- Aggregate amount attributable to transfers of value to such recipients i.e. the incentives and expenses (separate totals) for MR respondents
- Number of recipients (separate totals for fees and expenses required)
- % of all recipients that they represent (separate totals for fees and expenses required)

A copy of the ABPI template is available on the PMCPA website

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

- How this information must be disclosed

You must disclose the information through a central ABPI-sponsored online platform (currently in development) that will be open to the public. The information disclosed must remain in the public domain for at least three years from the time of disclosure.

- When must disclosure be made

Disclosure must be made in the first six months after the end of the calendar year in which the incentives/ expenses were paid.

- Consent

HCPs whose identity is or will become known to the commissioning pharmaceutical company must be told before fieldwork starts (generally at recruitment) what disclosure requires and ask for consent to pass on their personal data and their incentive/expenses information for disclosure. It must be clear to them:

- **why consent for use of their personal data is being requested**
- **how their personal data will be used, this includes who it will be given to**
- **of their right to withdraw their consent (at any stage)**
- **if they don't give consent, what the implications are**
- **how and who to contact if they have any questions.**

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

Consent may be given verbally during telephone recruitment/fieldwork or by clicking on an acceptance box if recruitment/fieldwork is carried out online or via a mobile device or in writing if recruitment/fieldwork is face to face.

The BHBA has provided a pro forma for a disclosure consent statement – see section M Pro Forma 3.

- Record keeping

Respondents' consent or refusal must be recorded.

Agencies must keep records of the disclosure information to pass to the pharmaceutical company.

Pharmaceutical companies must keep records of this disclosure information, then complete and upload the template on to the ABPI site.

Disclosures must be documented and records kept for at least five years after the end of the calendar year to which they relate.

Pharmaceutical companies must have appropriate and lawful arrangements in place to collect and transfer disclosure information.

Pharmaceutical companies should agree with their MR agencies a reporting schedule for disclosure information. The BHBA suggests that disclosure data is provided on completion of every MR project for which it is relevant.

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

- Patient organisations and MR-related payments

There are different requirements under the ABPI Code for MR-related payments made to patient organisations. Patient organisations are defined in EFPIA's 2011 Code of Practice on Relationships between the Pharmaceutical industry and Patient organisations as not-for-profit organisations (including the umbrella organisations to which they belong), mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers. The ABPI Code also refers to other user organisations such as disability organisations, carer or relative organisations and consumer organisations.

If a pharmaceutical company:

- provides financial support and/or significant indirect or non-financial support to patient organisations or other user organisations; and/or
- engages patient organisations or other user organisations to provide significant contracted services; it must make publicly available at national or European level a list of these organisations, which must include a description of the nature of the support or services provided that is sufficiently complete to enable the average reader to form an understanding of the arrangement or the significance of the support. The list of organisations must be updated at least once a year. Rule 27 of the ABPI Code contains further requirements relating to relationships with patient organisations.

Therefore, if patient organisations or other user organisations are either themselves the MR respondents (not a named individual) and the organisations receive a MR-related payment or they provide help recruiting patients/carers and receive a MR-related payment for this and the pharmaceutical company that commissioned the MR is aware of their identity under Clause 27 of the ABPI Code of Practice, the pharmaceutical company must make publicly available a list of these organisations.

The reporting process for this is not detailed within Clause 27 and patient organisations are not to be included within the reporting system set up for the Clause 24 disclosure requirements (for HCPs or HCOs). It is suggested that a list is published on the company website.

4.4 Recruiting from a list or database

- **You must always have a lawful basis for processing personal data, whether the data is readily available in the public domain or not.**

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.**

Some information in the public domain may be covered by a licence that restricts how the information can be used; always check to see if this is the case.

If a client company passed a list of doctors visited by sales representatives to allow an agency to draw a sample from it, the client company must have a legal basis for this data processing. For example the company must either have the consent of the people on the list to use their personal data for the purpose of MR or they must have conducted a legitimate interests impact assessment and determined that it is in their legitimate interests to do this.

You must not reveal the market research participants (i.e. who you interviewed from the list) to the client company.

- Sharing data which your company has purchased

Data you have 'purchased' from a data vendor as part of a syndicated service is likely to be licensed to you, i.e. you have the right to use the data but you do not own it. If you need to share the data externally with a third party e.g. an agency, you should check the re-distribution rules within the terms of the agreement/contract. The re-distribution rules will dictate if and how you are allowed to share the licensed data.

Often you'll be expected to complete a request for a Third Party Agreement (TPA) before any data can be shared with a third party. A TPA is an agreement which is signed by the 3 parties – the data vendor, the third party and yourself. TPAs are used to protect the data vendor from mis-use of their data.

- Revealing the source

When personal data is not obtained directly from the individual, the individual must be informed of the source of their personal data. Consequently this means identifying the client company if they provided the names but 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

- Correcting contact data

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

- Adding data

You can add further personal data to a database, only if you have a lawful basis for this e.g. you tell the respondent that you intend to do this, at the time of data collection and they give their consent.

You must also tell respondents why and for what purposes you will use the data, and that you will not release or use it for any non-research purpose unless they have separately agreed to this beforehand.

You can however make a data entry that you interviewed or contacted an individual on a given survey, or that they don't wish to be contacted for further research – if your sole purpose is to ensure they won't be unnecessarily re-contacted.

- Erasing data

You should respect any request from the respondent to have any or all of their personal data erased from a database at any time. **The right to have personal data erased is not absolute and applies only in specific circumstances e.g. you are relying on consent as your lawful basis for holding the data and the respondent withdraws their consent.**

- Opting out/'Do not contact' status

You must exclude anyone who has chosen to opt out or to 'not be contacted' for market research.

- Returning or destroying data

You must return or destroy client databases at the end of the project, telling the client first that you're going to do this.

When recruiting panel members, you must tell them that personal data will be stored for future research purposes.

4.5 Handling data

- Using and storing personal data

You mustn't use data collected at recruitment stage for anything other than the purpose respondents gave consent for. You're also not allowed to seek consent to use it for other purposes after the event.

You must store recruitment questionnaires, reimbursement records and attendance lists securely during and after the study. You mustn't hand them to the client without the consent of the respondent, and then they can only use them for MR purposes unless consent for another purpose was obtained up front.

You must keep copies of e-mails and other documents received from respondents agreeing to (or restricting) the use of or access to their personal information.

- Transferring personal data from one jurisdiction to another

You must not transfer personal data from one jurisdiction to another without the data subject's consent or other legally permissible grounds.

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

You must not transfer personal data outside the EEA unless there are adequate data protection measures in place. However the EU Commission provides a list of countries or territories providing adequate protection for data subjects in connection with the processing of their personal data, see the European Commission's data protection website at: <https://ico.org.uk/for-organisations/guide-to-data-protection/principle-8-international/>

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

- Using other legal grounds, such as consent from individuals for the transfer of their personal data for processing
- Reviewing and if necessary revising contracts, consider 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 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. Individuals must be told where data processing is based and given details of any data transfers to countries without adequate data protection.

For further information see: http://ec.europa.eu/justice/data-protection/international-transfers/index_en.htm

- Snowballing

When you're developing a list (and then a sample) by asking people to supply other people's names, you must tell the person being recruited how you obtained their name and have a lawful basis eg their consent, to process their personal data.

This fits with our principle of being transparent. This technique, or 'snowballing', is often used to identify opinion leaders.

When trying to recruit an opinion leader, you must tell the person e.g. the doctor that another one suggested them, but there is no need to provide the name.

4.6 Re-contacting respondents

- Gaining permission

You can only re-contact respondents if you 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.

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.**

- Re-contact questions

In order to gain consent, you must tell respondents who agree to be re-contacted what the purpose of this is and who will be contacting them (in terms of the organisation and roles, rather than names).

We recommend you include questions about the re-contact that relate to the study and clearly communicate their purpose e.g. a second stage of the study, to ask an extra question or explore an issue further. The question 'May we contact you for future research?' isn't sufficient. This type of question is really a panel-building question, as it relates to unspecified future projects. It also offers respondents the opportunity to opt out of all future projects by answering 'no', in which case you would never be able to contact them again.

4.7 Client company involvement in recruitment

Companies can recruit and field their own MR studies. All the conditions that apply to agency-led studies apply to company-run studies too.

- Contact name and sponsor identity

You must reveal the sponsor's name – you have to inform the respondent which organisation the interviewer is working for and/or who the data controller is and/or who is the recipient of their personal data.

- Confidentiality and security of personal data

You must keep respondents' personal details confidential and inaccessible to anyone outside the MR team or unit.

4.8 Recruiting patients through doctors

- Doctors may act as intermediaries in recruiting patients, by inviting them to take part or by passing on agency questionnaires. **If they do, they must:**
 - ensure patients understand it's their choice whether or not to take part
 - not disclose the patient's identity to the agency until they've agreed to take part
- **If patients reply directly to the agency, which is preferable, you must not tell the doctor which patients will or have taken part.**
- Beware of pressure placed on patients by a physician request and try to minimise any potential pressure e.g. use a written invitation rather than a direct request.
- You should avoid tying the reimbursement rate to the precise number of patients successfully recruited.

4.9 Reimbursing respondents

- Principles

'Reimbursement' is any benefit you give a respondent to encourage them to take part in a MR study (and is sometimes called an incentive). You should keep it:

- to a minimum amount
- proportionate to the amount of the respondent's time involved
- appropriate to the type of respondent and the nature of the task

Where incentives are offered, respondents must be clearly informed of the following:

- who will administer the incentive
- what the incentive will be
- when the participant will receive the incentive
- whether any conditions are attached e.g. completion of a specific task or passing of quality control checks

The incentive to be paid must be entirely clear and incentive fees must be specified separately from other recruitment costs including reimbursement for the cost of travel. Any payments to a respondent must be transparent, documented and agreed with the Client, including any changes to payment levels.

- How much?

There's currently no MR industry guideline or central source for standard rates of reimbursement. However, you should not reimburse more than the fair market value for professional consultancy or advice. If an incentive could be viewed as inappropriate or excessive it could be viewed as a bribe. The ABPI Code of Practice 2016 advises that the "compensation for the services must be reasonable and reflect the fair market value of the services provided". Borrowing from the ABPI Code – a useful criterion in determining whether the incentive is acceptable is to apply the question 'would you and your company be willing to have the incentive generally known?' The impression that is created by the incentive should be kept in mind.

You may offer a copy of the research report or findings as an 'incentive', even if it shows the client's identity, provided it doesn't contain any client promotional material. You may need the client's permission to do so.

Setting a fixed ceiling or cap on incentives and offering no flexibility is unhelpful and should be avoided. Offering a maximum and some scope for negotiation if this is considered insufficient or this proves to be the case during recruitment, is advised and fair market value should guide the maximum. It should not however be out of proportion to the task.

For patients and members of the public, it's a token of appreciation, not a fee for time.

You can offer a donation to a charity as an incentive, these qualify as a market related payment and have to be disclosed. Gifts are rare due to company policy or for tax reasons.

UK affiliate should be involved in setting and approving incentives levels for UK fieldwork when it is part of a multi-country study commissioned by a non-UK based arm of the business.

An allocation for respondent travelling time and expense should be considered for central location fieldwork. This allocation should be in line with the commissioning client company's policy. Any allocation made for travelling time and expenses should be transparent to the client company and to the respondent.

If respondents incur costs by participating in the MR e.g. telephone call charges, these should be reimbursed. **If any incurred costs are not to be reimbursed respondents must understand this in advance of fieldwork e.g. they could be told that telephone calls will be charged at their normal rate; premium rate phone numbers must not be used for MR.**

The time taken for any pre-work or homework should be considered and added to the length of the interview and so taken into account when the incentive level is set.

Minimum rates for participation in different types of market research should not be based on a pro rata approach alone. For example a £50 hourly rate may be appropriate; £12.50 for 15 minutes is not.

Commissioning pharmaceutical companies should be transparent and up front about any fixed rates or caps they have, these should be included in the brief and passed down the chain at the first opportunity.

Recognise that imposing specific screening criteria particularly criteria that effectively target popular sectors for market research e.g. high prescribers, will make recruitment harder and demand greater flexibility on incentives.

- How to handle it

Only your agency or in-house researchers must handle reimbursement.

Obtain receipts whenever practical. See our Receipts of Reimbursement form in section M Pro Forma 4.

- Free prize draws

You must not ask respondents to do anything other than agree to take part in a MR exercise or return a questionnaire, to be eligible to enter a free prize draw.

'Free' includes any method of communication (post, telephone or other) at a 'normal rate'. For further information see the MRS regulations for administering free prize draws:

<https://www.mrs.org.uk/pdf/Regulations%20for%20Incentives%20and%20Prize%20Draws%20July%202015.pdf>

- Panel members

You should let panel members know roughly the level of commitment and/or amount of time involved before they'll be reimbursed.

- Prohibited reimbursements

You must never offer a reimbursement that:

- could influence opinion or behaviour (e.g. excessive payments that look like an attempt to buy good opinion or reward buying behaviour)
- requires the respondent to spend money
- is made up of the sponsoring client's goods, services or vouchers
- is a covert means of collecting personal details (alongside supposed MR questions)

- Keeping reimbursement data confidential

You must keep the personal details of reimbursed respondents confidential:

- If you're in an agency, you must not pass these personal details to the client without a lawful basis such as consent. This consent must not be a condition of being reimbursed. You must ensure that reimbursed respondents' personal data is not accessible to anyone outside the agency, research team or company personnel involved in processing the reimbursement.
- If you're in an in-house MR department, you must ensure these personal details are inaccessible to anyone outside the research team or company personnel involved in processing the reimbursement.

5 Designing fieldwork



5.1 Question and questionnaire design

You must take reasonable steps to ensure:

- questions are fit for purpose
- questionnaires' design and content is tailored and relevant to the audience
- respondents are able to reflect their views in their answers to questions including 'don't know' and 'prefer not to say'
- respondents aren't led towards a particular answer
- interpretation of the answers will be unambiguous
- personal data you collect is relevant and not excessive

For more information on questionnaire design see the MRS Guidelines:

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

- Screening questionnaires

Screeners should be used purely for recruitment purposes and not data collection. All questions included should screen respondents in or out. Screening interviews should be concluded when a respondent is definitively screened out. Screeners are generally brief and potential respondents are not reimbursed for the time it takes to complete them. However if a screener is unusually long or complex, it is reasonable to reimburse those that have completed the full screener.

The BHBA's Response Rate Task Force has produced a report *Reversing the decline in HCP participation*, which makes recommendations to address the concerns that lead to healthcare professionals declining invitations to take part in market research. See details of the report:

<https://www.bhbia.org.uk/latestnews/news/responserates.aspx> For practical guidance on how to implement better screening practice, the BHBA Fieldwork Forum have created a Screener Design and Best Practice Guide – see details at: <https://www.bhbia.org.uk/latestnews/news/screenerdesign.aspx>

- Data minimisation

The collection of personal data within screeners, questionnaires and guides must be limited to only that which is necessary for the purposes of the work.

5.2 Disguised promotion

- Designing materials

You must not try to influence respondents' opinions or behaviours through the design of the questionnaire, the guide or the stimulus materials.

This is often called 'disguised promotion', 'selling under the guise of' or 'sugging'. See also The ABPI Code of Practice Clause 12.2. It is important within the introductions to recruitment screeners and interviews to make clear the purpose of the MR, particularly if you are including review of stimulus, such as brand names, product attributes, hypothetical scenarios, prices, product descriptions. It is important that respondents understand the nature of the MR that they will be participating in.

- Impact of the MR

You must not expect or ask respondents to change their attitudes or behaviour because of the MR. However, you can ask them whether a change might hypothetically be possible.

When researching any medical treatments (existing or potential) with patients you must not:

- raise unfounded hopes
- mislead about a product's safety
- encourage patients or other members of the public to ask their doctor to prescribe a product
- offer advice on the specific therapy area being discussed

Requests for advice on personal medical matters should be refused and the individual recommended to consult his or her doctor, prescriber or other health professional.

- Brand names and product messages

You must avoid brand names as much as possible. Using them unnecessarily or repeatedly could make your MR look like promotion. Use 'Product X' unless:

- reaction to the name or its visual representation is an objective

- using a name is essential to the interpretation of the stimulus, and this is in turn essential to the study
- objectives
- you need to refer to a specific product e.g. in brand tracking. If possible compare with other brands to reduce the product's standout and so reduce the risk of the MR being considered promotion

You must not use the brand name of an unlicensed product (unless you're testing the brand name alongside a range of options).

**You must not over-emphasise claims or product messages.
You must avoid unnecessary, repeated use of the brand name.**

5.3 Sensitive topics

A sensitive topic may affect all respondents because of its nature, or a particular respondent because of their history and experience.

When you need to discuss a sensitive topic you must make sure respondents know:

- **what the topic is before the interview**
- **an outline of the content**
- **they don't need to answer all the questions, you should offer a 'prefer not to answer' option**
- **they can withdraw at any point in the recruitment or interview process**

In cases where the subject under discussion is sensitive and gender-specific, you should consider the use of same sex interviewers, or offer the choice of a same sex interviewer.

If collecting information on sex, gender or age may prove sensitive, we suggest you consult the MRS's:

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

5.4 Stimulus material

Stimulus material is any material shown to respondents during fieldwork e.g. product profiles, patient information leaflets, advertising concepts, sales aids, packaging materials. It is visual, verbal and/or auditory material that is used to communicate certain ideas to enable them to be researched, or to stimulate discussion of relevant topics. It does not include questionnaires, screeners or discussion guides.

- Content

Stimulus material must be fit for purpose. The reasons for its use in a market research study must be clear and directly linked to the MR objectives (to avoid looking like disguised promotion).

You must ensure respondents understand when they're providing feedback on:

- **draft materials**
- **hypothetical scenarios, including the use of a conjoint attribute and level grid**
- **assumptions**
- **a product in development**
- **an unlicensed indication**

When using drafts or hypothetical scenarios etc. you should use introductory statements to set the scene e.g.:



The ABPI Code of Practice (Clause 7 Information, claims and comparisons) calls for information claims and comparisons to be accurate, balanced, fair, objective and unambiguous. They must be an up-to-date evaluation of all the evidence, and must not mislead directly or by implication, distortion, exaggeration or undue emphasis. We expect the same standard for stimulus material(s). The Code also highlights areas of

concern with regard to the content of promotional material. These give us some useful guidelines for the content of MR stimulus material. In summary:

- Beware of unqualified comparisons e.g. better, stronger
- Don't use 'safe' without qualification
- Beware of superlatives (e.g. the most, best)
- Don't describe a medicine which has been available for twelve months or more as 'new'
- Don't show children on or in association with products that aren't authorized for children

- Examination of MR Material

The ABPI Code of Practice states that MR material should be examined by the commissioning client company to ensure that it does not contravene the ABPI Code (certification is not required). The appointed person should be sufficiently familiar with the ABPI Code, and all MR materials i.e. screeners, guides/questionnaires and stimulus should be examined.

The BHBA provides online training specifically for non market research personnel involved in reviewing market research materials - see the online training section on the BHBA's website.

- Confidentiality agreement

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.

5.5 Testing products and devices

Sometimes respondents need to handle, use, apply or ingest a product (e.g. in taste testing or formulation acceptability). For legal and safety reasons, specific rules apply when using medicines in MR. Healthcare companies should refer to their medical and legal/regulatory departments for guidance when testing products and devices.

- Products being handled or taken
 - **Should be placebos wherever possible.**
 - **A patient can only take a licensed prescription only medicines (POMs) if a registered medical practitioner is present and if they are an existing user.**
If the POM is unlicensed, a Research Ethics Committee (<http://www.hra.nhs.uk/resources/applying-to-recs/>) needs to approve the respondent taking it.
 - **You must follow The Guidelines for Good Clinical Practice (GCP) if the product is licensed but you're asking the respondent to use it outside its licensed indication.**
http://ec.europa.eu/health/files/eudralex/vol-1/dir_2005_28/dir_2005_28_en.pdf
 - **If medical devices are to be tested that could be harmful (e.g. needles), that aren't CE (European Community) marked or that are to be tested off-license the healthcare client company's medical department must approve the MR approach, advise if a registered medical practitioner needs to be present or if there are any guidelines on medical devices that need to be followed.**

The company must provide full product/formulation details including all ingredients.

- Respondents must read and understand the details and then sign a disclaimer.

- Healthcare/pharmaceutical clients companies' responsibilities

When a client provides products to an agency researcher for the purposes of an MR study, the products must comply with the law and the client must provide all the necessary information on them to the researcher. Clients must provide correct directions for use, an ingredients/components list, and the transport and storage conditions. They must also inform the researcher of any requirements regarding the security of the products.

Clients are fully responsible for all damage or injury caused by anything they provided for research purposes, unless directions or instructions given were not followed when it was in the agency's possession (or the agency was otherwise in breach of any legal obligations, for example, it acted negligently).

6 Conducting fieldwork

6.1 Informing

Before fieldwork starts all of the information detailed in Section E4.2 Obtaining agreement, must be communicated to respondents.



6.2 Collecting adverse event (AE) reports

You must collect all adverse events (AEs), product complaints (PCs) and special reporting situations (SRSs) associated with the marketing authorisation holder's (MAH) drugs, whether or not there's a proven link to the drug or treatment.

For the full reporting requirements see the latest: [ABPI/BHBA Guidance Notes on the Collection of Adverse Events and Product Complaints from Market Research Programmes](#).

We also provide a [dedicated online training module on adverse event reporting](#) and strongly recommend you undertake this and the associated competency test to become certified, to assist you in fulfilling your ethical and legal obligations.

6.3 Observing and recording

Personal data includes sound and image data e.g. non-anonymised audio and video recordings from which an individual could be identified. **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 isn't likely to be identifiable data in isolation.**

- Restrictions on clients

At the start of the project, you must make clients fully aware of restrictions on observation or using recordings and how this might affect what they would like to see or listen to (copies of tapes or other primary materials) during or after the project.

- Informing respondents and getting their consent

You must inform respondents:

- if their input will be observed or recorded
- who will see the data – the organisation type and the types of people viewing, the organisation may need to be named depending how viewing takes place (see Actions for different viewing and recording methods involving the end client below)
- why ie what their data will be used for.

You must always get respondents' consent for viewing or recording even if those watching or listening in only have access to anonymised recordings.

You must obtain consent for each purpose the data will be used for.

Consent must be recorded.

You must always get respondents' consent for viewing or audio/video recording before this starts, i.e. at recruitment.

If non-anonymised viewing or recording via video-relay or streaming takes place you must name recipients of the personal data whatever the status of the recipients (eg agency or end client).

The end client's identity may be disclosed at the end of the interview IF naming them 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
- If the end client is receiving personal data they must be named before any transfer takes place
- The justification for this should be documented.

If non-anonymised personal data is to be recorded, respondents must be made aware:

- in what countries viewing/listening will take place
- of their right to withdraw their consent (at any stage)
- how and who to contact within the MR agency with any questions or concerns.

If a respondent doesn't want client personnel to view their non-anonymised input, you must respect this and anonymise it. Anonymised refers to disguising respondents' identity e.g. blurring of faces and/or disguising voices – i.e. 'non-anonymised' means that this has not been done.

- Actions for different viewing and recording methods involving the end client

See our form in section M Pro Forma 6.

Live viewing – via one way mirror or sitting-in

By one-way mirror or sitting in – you must tell respondents that the end client will observe them and respondents must consent to this beforehand.

- In this situation personal data isn't being transferred to the end client, so data protection legislation does not apply and so the end client may remain anonymous unless you are legally obliged to reveal their identity for another reason e.g. the end client is a data controller or the end client supplied the sample.
- Before fieldwork starts, you should agree and document the client position on whether you can reveal their identity to respondents if it's requested and if it can be revealed, when – during or at the end of the interview. You should reflect this in screener and interview materials, so that interviewers can react appropriately.

Live viewing – via video relay/streaming, with and without recording

Live viewing – via video relay/streaming, with and without recording - 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.

Delayed viewing – via video-relay (including video streaming and taping)

Delayed viewing – via video relay/streaming, with and without recording - 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 but 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

- Security for video-streaming

You must make sure that the video streaming service provider ensures the data is secure at all times. All parties involved in the video-relay process have data protection responsibilities to ensure the correct informed consents are in place (and appropriately recorded) and to safeguard personal data in transmission and storage. The data controller(s) are ultimately responsible under data protection legislation.

Remember it's essential to obtain respondents' informed consent before you archive recordings, this too requires naming of the client company assuming it is the data controller.

- Respondents withdrawing

Respondents can withdraw at any stage even at the end of a group discussion. You must remove their contribution from the final analysis and reporting.

6.4 Observer behaviour

- Introducing observers

You must introduce client observers openly and honestly to respondents.

You don't need to introduce them by name – just their roles within the company and general reasons for observing.

- Observers' responsibilities

You must obtain agreement from observers to abide by the following:

- **To withdraw from observing if they know a respondent (to protect the respondent's anonymity). They must also withdraw if they know they'll have direct contact with a respondent at a later date.**

However, if you inform a respondent that an observer who knows them is present (although you don't have to reveal the observer's name), and they give permission for that individual to observe, then the observer may do so. Be careful that respondents are completely comfortable when 'put on the spot'.

- **To respect the confidentiality of all information exchanged in MR interviews and groups and not:**
 - **record any respondent's personal data, or record any information in order to identify the respondent**
 - **make any separate notes or recordings that could be attributed to an individual respondent**
 - **try to influence how any respondent is approached in future for sales or promotion**
 - **use any information to amend or build databases**

It's good practice for you to get observers to sign that they agree to this. See section M Pro Forma 8 for a ready to-use form.

- Video streaming

When observers will watch a video stream in a remote location, you must ensure that respondents' rights are protected, as if the observers were at the research location.

When using a company to record, transmit and/or archive audio or video recordings, you must ensure that:

- **they (the commissioning company) obtain the required consents before recording, transmitting or storing personal data**
 - **unauthorised viewers cannot access recorded material. We recommend the commissioning company:**
 - **ensures comprehensive security measures are in place**
 - **password-protects access and restricts it to authorised users (identified through a unique login), and that only the project leader distributes login IDs and passwords**
 - **obtains written agreement from authorised users not to allow access to unauthorised personnel.**
- See Client Agreement to Safeguard Confidentiality of Recordings in section M Pro Forma 7.**

- Transferring recordings overseas

You must not transfer personal data outside the EEA unless there are adequate data protection measures in place – see section 4.5.

- Storing recordings

You must not store non-anonymised recordings for longer than needed to fulfil the purposes for which they were collected.

6.5 Collecting materials

You must collect all stimulus materials and products or devices (prototypes or actual) at the end of the interview.

The only exception to this is when a home trial follows the interview.

7 Analysing, reporting and publishing

7.1 Storing and accessing respondent data

- **Data minimisation**

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

- Security

If it's possible to link individuals to their responses, you must put in place adequate security to ensure the data is not accessible, even accidentally, to unauthorised individuals inside or outside your organisation. Security precautions are necessary for all types of personal data.

If you need to keep personal data (e.g. in the case of panel or longitudinal studies), you must store it securely to prevent any unauthorised access. You must obtain agreement from respondents before you handle their data in this way.



All those processing personal data must have a data breach notification policy and process in place.

- Information about respondents

You must tell respondents they can:
 - 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**

All those processing personal data must have policies and processes in place to allow them to put respondents'/data subjects' rights into practice.

- Researchers accessing data

You must authorise access only on a 'need-to-know' basis and solely for research purposes (including quality control auditing and monitoring).

You must not disclose non-anonymised data to anyone outside the research organisation(s) involved, unless respondents have given specific consent.

You can use anonymised and non-attributable responses without specific consent.

7.2 Reporting

- Principles

When reporting, you must ensure the research findings support your interpretation and conclusions adequately – and include an explanation outlining which data support your interpretation.

Your reports and presentations must accurately:
 - reflect the findings of the research
 - reflect your interpretations and conclusions
 - distinguish between factual reporting of data and your interpretation
Report or presentation content must not breach copyright. If you use images/visual information within your report or presentation, you must have the appropriate permissions to do this.
- Technical detail

You must include the technical detail necessary to assess the validity of the findings, including sample size, question source and statistical tests used.

When you present data in tables you must include sufficient technical information for readers to be able to interpret the results and their validity.
- Respondents' anonymity

When you make transcripts available, or include taped material or verbatims in reports or presentations, you must take care to preserve respondents' anonymity at all times. Personal data must not be included in reports unless consent has been obtained.

7.3 Publishing

- Agency approval of client publication

A client must not publish any survey results without the agency's approval (which may be contractual), unless agreed in advance.

You must check any materials clients have prepared to ensure the research results aren't incorrect or misleading.

The publication must refer to full source details and must include detail that will allow the audience to assess the quality of the data and the validity of the conclusions.
- Misreporting

If a client misreports MR, you must, as soon as possible:

- refuse permission for your name to be used in further connection with the misrepresented findings
- publish a statement declaring the results have been represented in a misleading way
- correct it by publishing the relevant technical details of the project

8 Closing off

8.1 Adverse events

You must keep a record of all adverse events sent to the client company so that reconciliation can be performed as required. See the latest [ABPI/BHBIA Guidance Notes on the Collection of Adverse Events and Product Complaints from Market Research Programmes](#) for full details.



8.2 Data

- Personal and non-personal data

To comply with the Data Protection Act 2018, you must securely destroy personal data when the purpose(s) for which you collected are redundant. Personal data must not be stored for longer than necessary.

You can destroy personal data (e.g. recruitment questionnaires) before non-personal data (such as tabulations).

There are no legislative requirements on how long you should keep anonymous data. This will depend on the nature of the data, type of project and the need for future research or follow-up analysis.

You should agree the period of storage with the client, ideally in advance.

- Destroying video streams

If you used video streaming for remote viewing of fieldwork, and the transmission system delivered a copy to the receiving computer, you must ensure that any copy on the observer's computer is deleted once the purpose for which it was made is redundant.

8.3 Storing contact details

Provided you have a lawful basis e.g. respondents have given their consent, you can keep their contact details on file to contact them about taking part in future MR. Respondents must have agreed to both:

- being contacted again
- their personal data being held on file

They must agree that they can be re-contacted even though the nature of the future MR isn't known.

This protects respondents from repeated, uninvited contact.

8.4 Security

You must take appropriate steps to ensure the safe handling, processing, storage, and disposal of MR and personal data.

You must design and organise your security to fit the nature of the personal data you hold and the harm that may result from a security breach.

You must be clear about who in your organisation is responsible for ensuring information security.

You must have appropriate administrative procedures, IT resources, technologies (e.g. reliable encryption systems, firewall, user identification, password access), robust policies and procedures and reliable, well-trained staff to manage these steps to best effect.

You must clearly label and store original copies of personal data in a restricted access area until they are destroyed.

You should ensure the method of destruction is adequate for the confidentiality of the data.

For further information please see the BHBIA's guide to Data Security available at <https://www.bhbia.org.uk/guidelines/gdprupdates.aspx>

F RESPONDENT TYPES



1 Patients

- Obtaining information for MR

Information from patient records can be used for market research without the patient's consent, only if the data is anonymous or if the patient gives explicit consent allowing the use of their non-anonymised data. Consent may not be the only lawful basis for this data processing purpose but it may be the most transparent. The objectives of the study must also fulfil a market research purpose.

- Simulated consultations

You can legitimately simulate consultations between a patient and a healthcare professional (who know or don't know each other). However, you should do so with great care. The PMCPA and MRS advise caution because it's likely to be difficult for the agency to guarantee the well-being of the patient. They suggest only highly trained interviewers do this. PMCPA advice suggests that if a doctor said something that concerned or confused a patient, the patient might be adversely affected by the research, and could have cause for complaint.

2 Vulnerable respondents

- Defining vulnerable

This refers to respondents who could be more susceptible than normal to physical or mental stress brought on by the research process. This could be due to their age, or physical or mental health.

- Interviewing

You should consider these questions if you think respondents might be vulnerable:

- Is the MR justifiable?
- Is the nature of the interview and tasks involved appropriate?
- Should a carer be present or on hand (if they have one)?
- Is extra time needed?

- Special planning

You should consider some special conditions and contingency planning for these interviews. For instance, female interviewers for female respondents may be appropriate, as would providing breaks, or offering to postpone or cancel the interview.

If you need any further detail upon the definition of 'vulnerable' or key points to remember please see the Best Practice Guide on Research Participant Vulnerability, January 2016, <http://www.mrs.org.uk/pdf/MRS%20Researching%20Vulnerable%20Participants%20best%20practice%20note.pdf>

3 Children and young people

You may wish to interview patients or sufferers who are under 18 years of age. See the *MRS Guidelines for Research with Children and Young People September 2014* for the full rules.

- Defining children and young people

In research terms, a 'child' is a minor i.e. 15 years old or under. A 'young person' is 16 or 17 years old. This reflects the UK MRS's definition but is different to the ESOMAR definition (which says that a child is 12 years old or less and a young person is aged 13 to 17).

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.

- Consent for children

- **Before asking a child whether they'll take part in MR, you must obtain and verify informed consent from the responsible adult (i.e. the adult responsible for the child's safety and welfare at the time of the research).**

- **A child must have their own opportunity to agree or decline taking part, and if they agree, must give explicit consent.**
- **You must record details of each person giving consent (name and role).**
- **For online research – when you know or ought reasonably to know that respondents may include children, you must first ask respondents their age and nothing else. If they are under 16, you must exclude them from any requests for further personal information, until you've obtained the necessary consent from a responsible adult.**

You should obtain all consents in writing. You should also obtain written confirmation to support consent given by email.

You should inform responsible adults in full about any products or stimulus material which the child may be asked to try or use.

- Personal data

You must not collect personal information relating to other people from a child or young person, unless it's to obtain consent from a responsible adult. The questionnaire must avoid classification questions that are unnecessarily intrusive or difficult for the child or young person to answer.

- Incentives

You should ensure these are suitable and acceptable for a child or young person's age, and appropriate to the MR task. If the reimbursement is monetary, you should provide it as vouchers and not cash.

If the incentive or reimbursement is for a child, you must inform the responsible adult of its nature and value when you ask for consent.

- Disclosure and Barring Service (DBS) Check

DBS checks may be necessary in some circumstances for interviewers but aren't necessary for all researchers. For more details see the MRS Guidelines for Research with Children and Young People, Criminal Record checks (p29).

- Other principles

- **You must never ask a child or young person to do something illegal for their age**
- **You must always use language on questionnaires that's suitable for the age of the children or young people**
- You should consider whether a responsible adult should be present during fieldwork

For further information on children and young people, see the MRS Guidelines:
<https://www.mrs.org.uk/pdf/2014-09-01Children%20and%20Young%20People%20Research%20Guidelines.pdf>

G METHODOLOGIES



The points made below are in addition to those made in previous sections.

1 Face-to-face

It's good practice to give the respondent the interviewer's identity card.

2 Telephone and mobile phone

- Mobile phones use

Take particular care when contacting respondents by mobile phone, voicemail, text message or email. Avoid unnecessary intrusion and respect their safety and privacy.

At the start of interviews by mobile and WAP phones, we recommend you ask a question such as 'Is it convenient to proceed with this interview now?'

You must tell respondents the likely length of an interview.

Calling back on a landline may be more convenient. You should find out as early as possible if the number you contacted, or will contact, is a mobile or a landline.

You must check any MR-specific 'do-not-contact' lists for mobiles as well as landlines and comply with telephone users' wishes.

- Predictive diallers

You should follow the MRS regulations on using predictive diallers i.e. any equipment capable of dialling a telephone number before a live operator handles the call.

- Apps

You must have a lawful basis e.g. consent to use an app to gather personal data from a respondent's device and tell them:

- what it does and why you want to use it
- the type of data it collects and what it will be used for
- anything affecting their data and communication:
 - the amount of data to be stored on the device
 - any data transfer requirements and the estimated levels
 - the type and frequency of notifications
- any impact on their device's performance such as reducing battery life
- how to remove the app from their device

We suggest you take legal advice if an app uses a location device or tracks activities without user engagement (e.g. passive listening) to ensure that you aren't contravening data protection or privacy rights.

MRS guidelines – extract from the Draft Mobile Research Guidelines August 2013:

6.1 Researchers must not:

- install software that modifies the mobile settings beyond what is necessary to conduct research
- install software that knowingly causes conflicts with the operating system or cause other installed software to behave erratically or in unexpected ways
- install software that is hidden within other software that may be downloaded or that is difficult to uninstall
- install software that delivers advertising content, with the exception of software for the purpose of legitimate advertising research
- install upgrades to software without notifying users and giving the participant the opportunity to opt out
- install software that inordinately drains battery life
- install software that causes any costs to the participant that aren't reimbursed by the research organization
- install or utilize geolocation tracking software that would compromise the participant or their personal data
- create a risk of exposing personal data during data transmission or storage
- change the nature of any identification and tracking technologies without notifying the user
- fail to notify the user of privacy practice changes relating to upgrades to the software
- collect identifiable data that may be used by the app provider for non-research purposes
- extract information from the mobile device or phone unless this information is part of the purpose of the study (and informed consent is obtained)

For more information on telephone methodology see the MRS Guidelines:

<https://www.mrs.org.uk/pdf/Guidelines%20on%20Privacy%20and%20Electronic%20Communications%2003.pdf>

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

[https://www.mrs.org.uk/pdf/2013-08-](https://www.mrs.org.uk/pdf/2013-08-30%20Draft%20AMSRS%20CASRO%20MRS%20Mobile%20Research%20Guidelines.pdf)

[30%20Draft%20AMSRS%20CASRO%20MRS%20Mobile%20Research%20Guidelines.pdf](https://www.mrs.org.uk/pdf/2013-08-30%20Draft%20AMSRS%20CASRO%20MRS%20Mobile%20Research%20Guidelines.pdf)

3 Observational (ethnographic)

This is any form of research that relies significantly on observations of human behaviour as a data source.

- Images and recordings

Images and audio recordings of people will be personal data for the purposes of the Data Protection Act 2018 and subject to the Act's requirements if any living person is identifiable (ie their identity can be established).

- Good practice
 - Clearly inform participants in writing of the exact nature of the research and each party's responsibilities – and obtain their written agreement to this
 - Before they agree to take part at recruitment, inform respondents of the extended nature of ethnographic research. Make timings clear
 - Inform respondents at recruitment of any activities you'll ask them to undertake
 - Use language that they'll understand
 - Explain significant factors that could influence whether they take part (e.g. discomfort, adverse effects or limitations on confidentiality)
 - Avoid unnecessary intrusion. You should build in safeguards and the ability to end the observation quickly, and you must respect their right to withdraw

For more information on observational methodology see the MRS Guidelines:

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

4 Online/internet

- Some definitions

Internet research, according to the MRS, is research in which a respondent, either once, or as part of a panel, is involved in any of the following:

- Completing research documentation online via any internet connected device
- Downloading research documentation from a server on the internet and returning it by e-mail
- Receiving research documentation incorporated into an email and returning it the same way
- Participating in an online qualitative interview or discussion (e.g. via a WebEx)
- 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

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

These guidelines apply to any market research you carry out on mobile phones or devices, and to browser-based or downloaded applications – whether you collect the data actively or passively.

An internet 'access panel' is a sample of potential respondents who declare they're willing to receive invitations to take part in future internet interviews.

Genuine MR e-mails (i.e. ones that contain nothing that could make the email be construed as for the purposes of marketing) aren't defined as commercial communications within the 2003 Privacy and Electronic Communications Regulations. So as long as clients have an appropriate lawful basis e.g. consent in place with recipients, they can forward customer e-mail addresses to agencies (for recruitment purposes) – unless of course they've included MR in their standard data protection opt-out policy.

- Costs

You must avoid respondents incurring costs.

- Informed Consent

If relying on informed consent you must give respondents an easy way of supplying it and withdrawing it. You must get consent from respondents to install and use software such as an app. You must also inform them of its purpose, the type of data it collects and any impact it will have on their device's functioning or performance e.g. reducing battery life.

- Personal data

A respondent's e-mail address or other personal identifier (e.g. screen or user name, or device identifier) is personal data where it can identify an individual. You must therefore ensure it's protected in the same way as other identifiers.

You must protect personal data collected or stored on websites or servers.

- Privacy notices

You must post a privacy policy statement/privacy notice on your website.

This should be easy to find, use and understand. It must include information such as what personal data is collected, how it is used, how it will be managed and the conditions under which it will be shared, as well as how to get more information or make a complaint.

You may also wish to consult the ICO Code of Practice for Data Protection Privacy Notices:

https://ico.org.uk/media/for-organisations/documents/1610/privacy_notices_cop.pdf

You must provide links to statements about privacy policy, data protection or cookie consent at the start of questionnaires.

This ensures respondents' rights are protected if they don't complete the questionnaire for any reason.

- Cookies

Under the Privacy and Electronic Communications Regulations you must obtain consent before placing cookies on a web-user's computer. This may be implied consent, but you must disclose the use of cookies. You must also clearly describe the data being collected and explain how it will be used. This information must be easily accessible.

- Panels

At recruitment, you must tell potential panel members that their personal details may be stored for further market research.

You must inform respondents that they're members of a panel, and you should remind them regularly.

You must also inform panel members of the sort of topics that may be covered, how their data will be used and the identity of the panel manager/data controller.

If you intend to set up and manage internet panels, see ESOMAR's support on recruiting the panel, project management, monitoring, maintenance, and data protection issues at <https://www.esomar.org/what-we-do/code-guidelines/28-questions-to-help-buyers-of-online-samples>. You can find more guidance in The British Standards Institution's standard for access panels: BS ISO 26362 (June 2009) at http://www.iso.org/iso/catalogue_detail?csnumber=43521

- Apps

For guidelines on the use of apps please see Apps on page 28.

- Survey length

You must tell respondents how long a questionnaire normally takes to complete (with a standard connection speed and no loss of connection).

- Selecting samples from lists

You must disclose the source of a list. If you obtained it from a website registration database, you must check that registration was voluntary and the data is current.

- Repeat and follow-up surveys

If you intend to do this, you must display on the respondents' screen by the end of the first interview, a privacy notice and a consent request to store their address data for the purpose of repeat and follow up surveys.

You should give respondents the opportunity to print these out.

You must include an option enabling them to refuse any further part in the survey, and to opt out of e-mail contact in connection with it.

- Giving contact details to respondents

You must tell them which particular researcher/organisation is carrying out the project, as well as their contact address. 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).

We recommend you provide a link to your website.

- Providing clear and full information

You should inform clients fully about the inherent risks of providing confidential information in internet surveys.

You mustn't mislead those using the research or the general public about the reliability and validity of internet research findings.

5 Social media

- Key principles

You must do no harm.

You must have a lawful basis to collect personal data e.g. consent or legitimate interests.

Respect the subject and their expectations of privacy.

- Passive MR – listening and scraping

You must observe the terms of use of online sites and services.

These may prohibit you from copying content (listening and scraping) without permission. You can however still read and précis it.

If copying content is allowed you must only report anonymised data unless you have a lawful basis eg participants have given consent for their personal data to be used for the purpose(s) that you intend to use it.

Consent is sometimes obtained as part of the terms of use (but you must consider whether in these circumstances they extend to your intended use and you are acting in compliance with data protection law).

You mustn't identify participants without their consent.

ESOMAR says that if you provide anonymised data to the client or another researcher, you must have a contract which requires the researcher/client not to attempt to use technical means to re-identify quotes or their posters and use such data for a non research purpose and to observe the ICC/ESOMAR Code and the provisions of this guideline. If a participant's comments will be made public (i.e. cannot be covered by contractual obligations) and the participant is easily identifiable, you must seek their consent or mask the comment.

You must only give clients quotations containing personal data if you have a lawful basis eg the participant has given their consent, and the client understands they mustn't use this to promote to the participant.

In private spaces (where users expect their comments to be private) you must obtain participants' consent to listen in and scrape comments, and to pass them on verbatim to clients. Other lawful bases are unlikely to be appropriate in this circumstance.

If you mask comments, you don't need to get permission from contributors. Masking means changing the comments such that they cannot be traced back to the contributor.

See the ESOMAR Guideline on Social Media Research for more information.

- Active MR – engaging with participants

You must observe the terms of use of online sites and services.

Some prohibit you from collecting any data.

You must obtain consent from the site and service owners and participants/users.

You must declare your presence and not give the impression that you're anything other than a market researcher.

You must tell participants which organisation is carrying out the research, what the purpose is, 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.

You must give participants your or the research agency's contact details. 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).

You must publish a privacy notice on your website.

Online space for MR, such as market research online communities (MROCs) must provide participants with information about what the MR is for, how their contributions might be used, and that the data will be shared with the client, plus

- any rules for interacting
- a site privacy notice
- protection of their personal data

- Observing copyright

If you use images/visual information lifted from social media/an online site, you must have the appropriate permissions to do this. You must not breach copyright by doing this.

6 Using sales representatives as interviewers

Historically, sales representatives (reps) have sometimes been involved in gathering MR data. We strongly advise against this because:

- reps aren't professionally trained interviewers, and may not be familiar with professional MR codes and legal requirements
- the research may be more vulnerable to an accusation of disguised promotion
- respondents are less likely to feedback openly and accurately
- reps cannot handle reimbursements (under the ABPI Code of Practice Clause 15.3)

If sales reps are used to gather information for a MR purpose, you must make sure:

- **respondents know which company the reps work for and their position**
- **information gathering is separate from any promotional visit.**

Please see the ABPI Code of Practice, Clause 19, Supplementary Information, for general guidance and further information.

Reps might be involved in a mock discussion with a doctor before testing a sales aid, but you should limit their role to delivering the sales story. You shouldn't involve them in collecting or analysing the information.

7 Testing sales aids

- The process

Typically, a company representative, or another member of staff, conducts a mock detail (sales visit to a doctor) using draft materials. The researcher, then interviews the doctor. You should ensure that everyone involved understands that this is a mock detail, staged purely for MR purposes and that the information presented may not be in its final form. You're allowed to 'close the sale' in the mock detail, but this doesn't constitute any kind of commitment. We recommend that you ask the respondent to sign that they're aware of these facts. See our form in section M Pro Forma 5.

- Conditions

The rep and the respondent should not know each other.

The commissioning company should try to make sure the rep is 'off territory' – and has not worked in that geographical area previously. If a rep recognises a respondent, they should not conduct the mock detail or take any part in the research.

The rep should not have any further contact with the respondent during the MR outside the mock detail.

When it's over, the rep should leave the room and remain out of view. The rep should not view any MR interviews that follow, unless you tell a respondent that this will happen (and obtain the respondent's consent if necessary).

- Duration

You must agree this with the rep.

It shouldn't be longer than necessary to present the materials to the respondent. Once you have agreed it, you should ensure that the rep doesn't exceed it.

- Stimulus

Reps must not leave the mock detail aid or any other material with respondents.

- Competitor testing

You must inform respondents beforehand that the research sponsor is not the company marketing the product concerned. You must ensure:

- **copyrights are not infringed**
- **competitor products are not misrepresented**
- **all material used is presented as a fair reflection of information available**
- **competitor companies or products aren't disparaged**

8 Follow-up studies of representatives' visits

- The process

Typically this involves recruiting doctors from a call list supplied by the commissioning company. You can interview doctors that a sales rep recently visited to assess their recall and the impact of both the visit and the sales material.

- Using contact lists

Under data protection legislation:

- **researchers using lists must have a lawful basis for the use of any personal data**
- **the agency must be under contract to the client, working as their agent to ensure protection of the data**
- **you need to ensure that there is a third party agreement or non-disclosure agreement and adequate**
- **consent has been established in place if the client company leases it lists from a data supplier**

- the agency must not add the data to any of its own databases without obtaining the respondents' permission beforehand
- you should destroy the sample lists or return them to the client at the end of the project

If you use lists of named individuals, you must reveal the source of the list during the interview.

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

If list details are incorrect, you can tell the list supplier (the data controller).

H SOME IMPORTANT DEFINITIONS



1 Market research (MR)

Market research attempts to generate understanding and knowledge of a market place and its consumers' behaviour. It does this by obtaining information (data) from specific samples of consumers and extrapolating results to the population as a whole. MR is scientifically conducted, and respondents' identity and all other personal data are confidential and not disclosed or used for any non-research purpose.

- It is not a commercial communication or a selling opportunity
- It has no interest in the individual identity of respondents
- It does not result in direct action relating to individuals or organisations named in it

A piece of work's objective(s) and approach (not its title or those commissioning it) define whether it's MR. So a series of interviews undertaken to obtain representative anonymised feedback is probably MR, whether e.g. Corporate Affairs, Market Access, PR Competitor Intelligence or branding professionals commissioned the work, and whatever the study is known as internally.

Advisory boards may or may not qualify as market research depending how they are run. An advisory board is generally a group that provides non-binding strategic advice to the management of an organisation. They often provide expert advice on emerging products or developments. If the advisory Board is recruited and operated as market research meeting the definition above, then it is market research.

2 Non-research purpose

Market research must be clearly distinguished from non-research practices or purposes.

Non-research is when data is collected for some reason other than enhancing our understanding (in a robust, scientific way), i.e. for any other purpose than described above.

- General characteristics
 - No guarantee of anonymity and confidentiality
 - Data identifies individuals so that direct action (such as selling or direct marketing) can take place
 - Respondents may be selected randomly and encouraged to express generalized views (rather than systematically targeted from specific sectors of the population and carefully focused on generating robust, validated data)
 - Promotes the aims, ideals, products or services of the sponsor

This reflects the MRS's *Regulations for Using Research Techniques for Non-Research Purposes Nov 2010*.

- Building databases

These require information about individuals which cannot be treated confidentially. Therefore, unless informed consent is obtained at recruitment, MR data cannot be:

- placed onto a client database
- used to develop customer intelligence for direct promotion
- used for direct marketing

For more information about non-research purposes see the MRS Guidelines:

<https://www.mrs.org.uk/pdf/2012-02-23%20Regulations%20for%20Non%20Research%20Purposes.pdf>

3 Research Ethics Committee approval

MR does not require the approval of the Research Ethics Committee (REC) because it falls outside the remit of the Research Governance Framework (RGF).

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

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213753/dh_133993.pdf

2.3.14 Healthcare market research⁷ may be undertaken by professional market researchers on behalf of pharmaceutical or medical device companies. Where such research is conducted by professional market researchers in accordance with the Legal and Ethical Guidelines issued by the British Healthcare Business Intelligence Association (BHBIA), it does not require REC review except where otherwise required by law, e.g. if it requires approval under the Mental Capacity Act. The BHBIA guidelines require that informed consent is obtained from patients for provision of any personal data or to undertake additional procedures such as questionnaires or interviews.

The National Health Service Health Research Authority (NHS HRA) provide a leaflet 'Defining research' that is designed to help you decide if a project is research, which normally requires review by a Research Ethics Committee (REC), or whether it is some other activity such as audit, service evaluation or public health surveillance. <http://www.hra.nhs.uk/documents/2016/06/defining-research.pdf>. They also provide a decision support tool to help determine whether a study should be classified as 'research' or not. <http://www.hra.nhs.uk/research-community/before-you-apply/determine-whether-your-study-is-research/>

EphMRA provides a detailed overview of the differences between market research (MR), non-interventional studies (NIS) and patient support programmes (PSP) within its Code of Conduct (section 3B, 3.9) available on the EphMRA website www.ephmra.org. EphMRA point to the following key distinction

"Non-interventional research is carried out for a clinical purpose i.e. to assess safety, efficacy or pharmacokinetics; market research is carried out for a commercial purpose i.e. to investigate market behaviour and opportunities, clinical endpoints are not needed for market research."

4 Disguised promotion

Concern about whether a project may be seen as or is judged to be disguised promotion may rest on a number of factors – see the list below. It may be the cumulative impact of several factors that influences perceptions or judgements.

- At recruitment and in the introduction to the MR explain clearly what is involved
- Justifiable business need and market research objectives
- Minimum sample size and appropriate sample structure
- Appropriate incentives to the time, tasks and types of respondent
- Balanced guide/questionnaire and stimulus design
- No unnecessary use of brand names
- No over-emphasis upon claims or product messages or attributes
 - Flag up the use of stimulus at recruitment and in the introduction to the MR
 - Make respondents aware that the stimulus is non-promotional and for the purposes of the market research alone
 - Make it clear if stimulus refers to a marketed or an unlicensed product
 - Limit the number of times the stimulus is shown to the minimum
 - If repeated exposure is required, explain why this is necessary
- Only collect essential personal data and explain why this is necessary
- Do not run market research alongside a non-research exercise

5 Personal data and data protection

The GDPR defines personal data as

"any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person"

Personal data that has been pseudonymised can fall within the scope of the GDPR depending on how difficult it is to attribute the pseudonym to a particular individual. If you have the means to reverse the pseudonymisation within your organisation, the pseudonymised data should be treated as personal data.

Personal data includes electronic, manual and recorded data held in alphabetical, numerical, graphical, photographic or acoustic form. Audio that could identify an individual and image data also qualify. Personal data may be a single piece of information or a series of pieces of information which together allow identification of an individual.

Once data has any identifiers linking it to a natural person removed, it's no longer personal data or covered by the Act. However researchers must make sure that de-identified data cannot be traced or an individual's identity inferred by deduction.

- **Special category (previously referred to as sensitive) personal data**

This includes information about race or ethnic origin, political opinions, religious beliefs, trade union membership, physical or mental health, sexual life, offences commissioned or carried out, whether alleged or committed. **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.

- Processing

You must process personal data in accordance with the Data Protection Act including: collecting, recording, organising, storing, altering, retrieving, using, disclosing, disseminating, aligning or combining, blocking, and erasing or destroying.

For more information on data protection and the Data Protection Act see:

<https://www.bhbia.org.uk/guidelines/gdprupdates.aspx>

<https://www.mrs.org.uk/standards/gdprsupport>

<https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/introduction>

6 Adverse events

An adverse event (AE) is any untoward medical occurrence or incident that a patient or clinical trial subject experiences when they use a medicinal product. This can be any unfavourable and unintended sign, symptom or disease associated in time with the use of the product, whether or not the product may have caused it.

An AE is distinct from other instances:

- Product complaint (PC)

This relates to a product or its packaging, not its effect on the patient e.g. damaged or missing tablets, wrong strength or colour of tablets, or a missing patient information leaflet.

- Special reporting situations

In some specific scenarios you need to collect data even if there is no associated AE e.g. used during pregnancy, overdose and off-label use.

For more information on all of these, see the latest **ABPI/BHIA Guidance Notes on the Collection of Adverse Events and Product Complaints from Market Research Programmes.**

7 Informed consent

"Informed consent is a process by which a participant voluntarily confirms his or her willingness to take part in a particular project, after having been informed of all aspects of the project that are relevant to their decision to participate."

MRS Code of Conduct, September 2014

You must make sure that respondents give their informed consent before information is collected from them.

The GDPR and 2018 Data Protection Act defines consent as

"any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her"

- **Explicit consent**

Although not clearly defined within the GDPR Explicit consent is basically a slightly higher standard of consent and is necessary for (amongst other things) processing special category (sensitive) personal data such as health or financial data. Explicit consent must be confirmed in a clear and specifically worded statement (oral or written), so signing a statement would be explicit consent but an affirmative action alone such as responding to an email requesting consent would not be explicit consent.

- Right to withdraw consent

All those that provide their consent for the processing of their personal data have the right to withdraw their consent at any time they chose. It must be as easy to withdraw consent as it was to give it, so it should be an easily accessible single step. It is good practice to tell individuals how to withdraw.

This is a key principle of the MRS Code of Conduct and is part of informed consent. Never pressurise respondents to complete an interview if they are uncomfortable, or to undertake tasks or discuss subjects they haven't been prepared for.

8 Confidentiality and anonymity

- Respondents

Respondents' confidentiality and anonymity must be preserved unless they have given their informed consent for their details to be revealed or for attributable comments to be passed on.

A respondent's anonymity isn't protected simply by withholding their name. You breach it by providing any information which when used alone or in combination with other available information could identify the respondent.

You must take reasonable measures to make sure that anonymisation is effective, bearing in mind both developments to technology and the context or environment in which the data will be viewed or used. Anonymisation might be compromised when eg sample sizes are small and made up of opinion leaders or when other information can easily be added.

- Patients

Under the 2018 Data Protection Act, information on an individual's physical or mental health is classified as special category personal data' and requires explicit consent to be obtained and used.

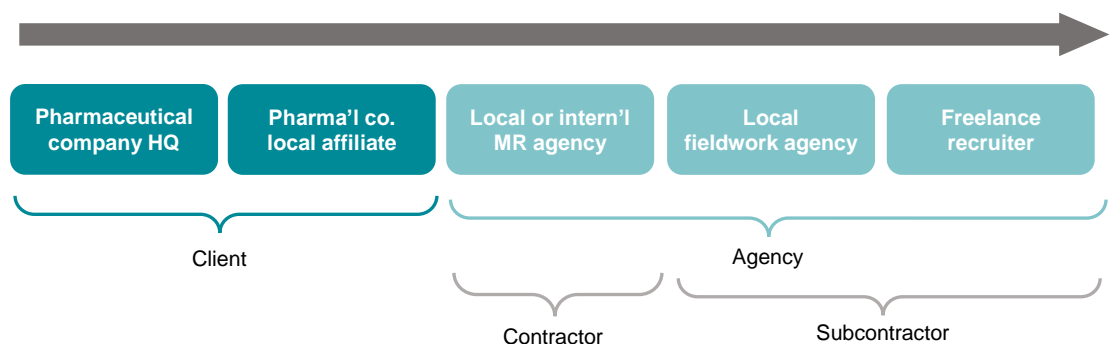
- Client Companies

You must not identify the clients or any confidential client data without the client's consent except if there is a legal obligation to do this eg the client is a data controller or supplied the sample or will receive respondent personal data. If the client company wants to exclude potential respondents that do not agree to wait until the end of the interview to know the client's name (if it has to be revealed), this is permissible as long as it's not detrimental to the individual.

9 Client and agency

In terms of our guidelines, the client is the commissioning party and the agency is the party executing the study on their behalf. Usually the client is a pharmaceutical manufacturer and the agency a MR specialist.

Because some studies involve more than one client and more than one agency, the following definitions apply for the purposes of our guidelines:



I DATA PROTECTION LEGISLATION



1 Requirements

You must make sure that your MR conforms to the Data Protection Act 2018.

- Responsibilities

The UK Data Protection Act 2018 is administered and enforced by the independent Information Commissioner's Office.

Under the GDPR, the data protection principles set out the main responsibilities for organisations.

Article 5 of the GDPR requires that personal data shall be:

"a) processed lawfully, fairly and in a transparent manner in relation to individuals;

b) collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall not be considered to be incompatible with the initial purposes;

c) adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed;

d) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay;

e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes subject to implementation of the appropriate technical and organisational measures required by the GDPR in order to safeguard the rights and freedoms of individuals; and

f) processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures."

- Data processing

'Processing' means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

- Controller and processor roles

A data controller is a person who (either alone or jointly or in common with others) determines the purposes for which and the manner in which any personal data are, or will be, processed. Data Controllers must pay a notification fee to the ICO; this replaces the previous registration process and fee (for further information on the fee, please see <https://www.bhbia.org.uk/latestnews/news/iconewfees.aspx>).

A data processor is any person (other than an employee of the data controller) who processes data on behalf of the data controller. For example, any contractor who processes data on the controller's behalf.

Controllers must only use processors which are able to guarantee that they will meet data protection requirements and protect the rights of data subjects.

Whenever a controller uses a processor there must be a written contract in place. Similarly, if a processor employs another processor it needs to have a written contract in place. The contract must state details of the processing, and must set out the processor's obligations. This includes the standards the processor must meet when processing personal data and the permissions it needs from the controller in relation to the processing.

The ICO advises that contracts must set out the:

- subject matter and duration of the processing; the nature and purpose of the processing;
- type of personal data and categories of data subject; and
- obligations and rights of the controller.

Contracts must also include as a minimum the following terms, requiring the processor to:

- only act on the written instructions of the controller;
- ensure that people processing the data are subject to a duty of confidence;
- take appropriate measures to ensure the security of processing;
- only engage sub-processors with the prior consent of the controller and under a written contract;
- assist the controller in providing subject access and allowing data subjects to exercise their rights under the GDPR;
- assist the controller in meeting its GDPR obligations in relation to the security of processing, the notification of personal data breaches and data protection impact assessments;
- delete or return all personal data to the controller as requested at the end of the contract; and
- submit to audits and inspections, provide the controller with whatever information it needs to ensure that they are both meeting their Article 28 obligations, and tell the controller immediately if it is asked to do something infringing the GDPR or other data protection law of the EU or a member state.

Your processor should not employ another processor without your prior specific or general written authorisation. Sub-processors do not have to be named in contracts as the list of sub-processors is subject to late changes or changes mid-project so it's not practical to name all individuals/organisations and it is sufficient to name types of sub-processors (e.g. recruiters, interviewers). If a processor employs a sub-processor, then it must impose the contract terms on the sub-processor.

For further details see:

<https://ico.org.uk/media/about-the-ico/consultations/2014789/draft-gdpr-contracts-guidance-v1-for-consultation-september-2017.pdf>

- **Data Protection Officer (DPO)**

DPOs are required for organisations whose core activities involve:

- either regular and systematic monitoring of data subjects on a large scale or
- large scale processing of special category data and data relating to criminal convictions.

Appointment of a DPO is likely to be a requirement for many MR suppliers. For further information about appointment of DPOs see the BHIA's guide <https://www.bhia.org.uk/guidelines/gdprupdates.aspx>

J HANDLING CONTRAVENTIONS AND COMPLAINTS



1 Who's responsible

- If a BHBA member works for another member – both parties are responsible for compliance (e.g. a MR agency works for a client company, or a freelance researcher works for an agency).
- If a BHBA member works independently – sole responsibility.
- If a non-member is sub-contracted to work for a BHBA member, and is under contract to adhere to the Guidelines – both parties are responsible (e.g. an independent recruiter who isn't a BHBA member is subcontracted to recruit a series of doctors for a member agency, and breaches the Guidelines by failing to gain the doctors' fully informed consent to take part).
- If a non-member works for a BHBA member, but isn't under contract to adhere to the Guidelines – the member alone is responsible.

2 The process

- We first investigate any breaches of the Guidelines and complaints ourselves.
- We may refer any concerns or complaints that we uphold to other industry regulators. They may then take disciplinary measures. Generally speaking, complaints that market research has been used as disguised promotion will be referred to and investigated by the PMCPA.
- If the Data Protection Act is breached, the Information Commissioner's Office (ICO) can take action. If they think the law has been broken, they can advise the offending organisation and ask it to solve the problem. In the most serious cases the ICO can impose fines.

For more information about contraventions and complaints see:

https://www.mrs.org.uk/standards/how_to_complain

<http://www.pmcpa.org.uk/thecode/Pages/Complaints-process.aspx>

<https://ico.org.uk/concerns/>

K KEY TERMINOLOGY

Agency Any individual, organisation, department or division, (including any belonging to the same organisation as the client) that is responsible for, or acts as, a supplier on all or part of a research project.

Anonymity Two interpretations: non-disclosure of a client's identity; protection of respondents' identities.

Anonymous data Data that does not relate to an identified or identifiable individual, the data subject is no longer identifiable. Anonymous data is no longer personal data.

Client Any individual, organisation, department or division (including one belonging to the same organisation as the researcher) which requests, commissions or subscribes to all or part of a MR project.

Confidential research Does not disclose personal details at an identifiable level.

Consent The freely given specific and informed agreement by a person (i.e. the 'data subject' or 'respondent') to take part in the MR and the processing of their personal data.

Consultant Any individual or organisation that provides research services, including subcontractors.

Data controller alone or jointly with others, determines the purpose and means of the processing of personal data.

Data processor processes data on behalf of the data controller.

Data subject A living identifiable person on whom personal data is held.

Digital listening Extracting data from social media for analysis, automatically or manually.

Disguised promotion Refers to promotion that is disguised as market research or market research that includes promotion.

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 such as health or financial data. Explicit consent must be confirmed in a clear and specifically worded statement (oral or written), so signing a statement would be explicit consent but an affirmative action alone such as responding to an email requesting consent would not be explicit consent.

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

Identity Information, as well as the name and/or address, from which recipients might identify respondents.

Internet access panel A sample of potential respondents who declare they are willing to receive invitations to take part in future internet interviews.

Interview Any form of direct or passive contact with respondents where the objective is to acquire data or information that could be used in whole or in part for the purposes of MR.

Interviewer Person who collects data from respondents for market, opinion, social, or healthcare purposes.

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

MROC (Market Research Online Community) a common term for an online community created specifically for market, social and opinion research. Others include DORC (Dedicated Online Research Community).

Observational research Methodology that relies significantly on the observation of human behaviour as one of its data sources.

Passive social media monitoring Extraction of data from social media for analysis where there is no interaction with the contributor. Also known as digital listening or scraping.

Personal data 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..

Primary market research generates original data directly from respondents to solve the problem in hand. Primary data is derived from new and original research designed to address a specific purpose.

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

Processing of personal data 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.

Profiling Means any form of automated processing consisting of the use of personal data to evaluate certain personal aspects relating to an individual, in particular to analyse or predict aspects of the individual's performance, preference, behaviour or health.

Promotional or sales activities Designed to change consumers' attitudes towards products or services in order to encourage them to buy or take these up.

Pseudonymisation This means the processing of personal data in such a way that the personal data can no longer be attributed to a specific data subject eg all identifiers have been removed and are stored separately. If the means to reverse the pseudonymisation are available within an organisation, the pseudonymised data is still classed as personal data.

Public domain Information, which is published and generally accessible or available to the public. Content that no one owns or controls, with intellectual property 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 could reasonably expect to be observed and/or overheard by other people (e.g. in a shop or on the street).

Public relations activities Designed to enhance public perceptions of bodies, organisations etc.

Record Any brief, proposal, questionnaire, respondent identification, check list, record sheet, audio or audio-visual recording or film, tabulation or computer printout, 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 – the most comprehensive information a project is based on, including not only original data records, but anything needed to evaluate those records e.g. quality control documents
- Secondary records – any other records about the respondent and the research results

Recruiter The person who identifies and invites respondents to take part in a MR project.

Researcher Any individual, agency, organisation, department or division that offers their services, carries out, or acts as a consultant on a MR project. Includes client organisations' in-house departments.

Respondent Any individual or organisation from which a researcher seeks any information. This can be obtained by verbal interviewing techniques, postal and other self-completion questionnaires, mechanical or electronic equipment, observation, and any other method where the identity of the provider may be recorded or is otherwise traceable.

Secondary market research Data already collected for one purpose is then re-analysed for another.

Sensitive or special category personal data Personal information which identifies a living individual and includes reference to: the racial or ethnic origin of the data subject; 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.

Scraping Extracting data from social media for analysis, either automatically or manually.

Screener Questionnaire used to identify suitable respondents (based upon pre-determined selection criteria) for a market research exercise

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

Stimulus material Material shown, referred to or read out to a respondent during the course of fieldwork.

Subcontractor An individual or organisation that undertakes a part of a research project (such as the fieldwork) under the instruction of the MR agency (the contractor).

Syndicated market research MR that is shared (both the findings and the costs) by a number of clients. However the market research agency owns the data.

Transparency Ensuring individuals have a very clear and unambiguous understanding of why the data is being collected and how it will be used.



Our guidelines draw on the following sources. You must ensure that you read and consult the relevant sources.

Supporting codes and legislation

The following codes have been invaluable in helping us. We've designed our guidelines to complement, rather than replace them:

- ABPI Code of Practice for the Pharmaceutical Industry 2016
- Market Research Society's Code of Conduct 2014
- ICC/ESOMAR International Code on Market, Opinion and Social Research and Data Analytics 2017

The following legislation is also vital in underpinning our guidelines:

- The Data Protection Act 2018
- 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)
- The Privacy and Electronic Communications (EC Directive) (Amendment) Regulations 2011

Other sources

- EphMRA – European Pharmaceutical MR Association
 - EphMRA Code of Conduct 2017
- ESOMAR – The European Society for Opinion and Marketing Research
 - Guideline for Online Research 2015
 - Guideline for Conducting Mobile Market Research October 2012
 - Guideline on Social Media Research July 2011
 - Guidelines on the Mutual Rights and Responsibilities of Researchers and Clients Oct 2010
 - How to Commission Research 2009
 - Interviewing Children and Young People 2009
 - Distinguishing Market Research from Other Data Collection Activities March 2009
 - Passive Data Collection, Observation and Recording February 2009
- Government Organisations
 - Information Commissioner – Guide to the General Data Protection Regulation (GDPR)
 - NHS – Notes on the Research Governance Guidelines for Health and Social Care
- MRS – Market Research Society
 - Administering Incentives and Free Prize Draws July 2015
 - Best Practice Guide on Research Participant Vulnerability, January 2016
 - Code of Conduct 2014
 - Guidelines for Research with Children and Young People September 2014
 - Data Protection & Research: Guidance for MRS Members and Company Partners 2018
 - Guidelines on the Privacy and Electronic Communications Regulations May 2011
 - Draft Mobile Research Guidelines August 2013
 - Guidance Note on Collecting Data on Sex and Gender January 2016
 - Guidance Note on Researching Age Bands for Over 65s, July 2016, (draft)
 - Guidelines for Online Research September 2014
 - Guide to Observers' Legal & Ethical Responsibilities October 2015
 - Online Data Collection and Privacy Discussion Paper July 2011
 - Online Data Collection and Privacy Response to Submissions April 2012
 - Qualitative Research Guidelines incl. Observational, Ethnographic and Deliberative Research September 2014
 - Questionnaire Design Guidelines September 2014
 - Use of Predictive Diallers March 2017
 - Using Research Techniques for Non-Research Purposes June 2014

Pro Forma 1 – Recruitment Script Template for use in conjunction with recruitment agreement (see Pro Forma 2)

Recruitment Script Template
This pro forma will need to be tailored to the project and the medium (face to face, telephone, online). It has been designed to encourage a simple, concise and consistent approach to recruitment.
My name is <name> from <company name> , an independent <company type> . We are conducting market research on behalf of a <name or type of company sponsoring the MR> and would really value your opinion.
[IF NECESSARY] We would prefer not to reveal the name of the healthcare/pharmaceutical company until the end of the interview, just in case knowing this biases any responses. Is this acceptable to you or not? YES NO IF NO, THE NAME MUST BE REVEALED BEFORE THE INTERVIEW TAKES PLACE OR THE INTERVIEW TERMINATED IF THIS IS NOT DETRIMENTAL TO THE INDIVIDUAL.
The purpose of the research is to <purpose> and it will take the form of <interview type, duration, start time & location> . We will provide a payment of <amount> paid by <method of payment> at <time/place> . <Travel expenses will also be covered.>
Taking this opportunity to have your voice heard would greatly help us further our research, and your participation would be hugely appreciated. If you have any questions, please contact <name> at <company name> by email <email address> and/or call this number <telephone number> .
Privacy
The research will comply with UK Data Protection law and with the British Healthcare Business Intelligence Association's Legal & Ethical Guidelines.
Any information you provide us with will be treated as confidential, it will be combined with feedback from others like yourself. You will remain anonymous unless you give permission to be identified.
Your information will only be used for <purpose eg market research> and will not be passed to any other organisation without your permission.
IF PERSONAL DATA DID NOT COME DIRECTLY FROM THE INDIVIDUAL: We obtained your details from <name source> .
You have the right to refuse to answer questions or withdraw at any time. For more information about your rights please see our privacy notice, it is available at <privacy notice location> .
We need your consent in order for us to collect and use any information about you. We won't keep any personal data you give us for longer than <months/years> for <purpose> .
The <interview/group discussion> will be <watched as it happens through a one way mirror/audio and/or video recorded> for <purpose(s)> . The recording will only be available to <agency/company & client roles> . DEMONSTRABLE CONSENT FOR RECORDING MUST BE OBTAINED AND MUST BE SPECIFIC TO EACH PURPOSE, THIS MAY BE PROVIDED AT THE START OF FIELDWORK.
IF DATA IS BEING TRANSFERRED OUTSIDE THE EU: We may need to send some of your personal data outside of the European Economic Area to <country> because <reason> . We will make sure that it is kept secure at all times.
AE Reporting: HCPs
We are required to pass on to our client details of adverse events/product complaints pertaining to their products that are mentioned during the interview. If this happens, we will need to collect details and report the event, even if you have already done so via the MHRA's 'Yellow Card' system. You will be asked whether you consent to us passing your details to the client company's drug safety department for their follow up, but you may choose to remain anonymous. This will have no impact on the confidentiality and anonymity associated with the interview itself.
AE Reporting: Non-HCP - patient, caregiver or consumer
We are required to pass on to the sponsoring client any details of side effects or product complaints relating to their products that are mentioned during the interview. This is to help them learn more about the safety of their medicines. If this happens, we will need to collect details and report the side effects or product complaint. You will be asked if you give permission for us to pass your contact details to the company's drug safety department for them to follow up. This will have no impact on the confidentiality and anonymity associated with the interview itself.

Pro Forma 2 – Recruitment Agreement to be used in conjunction with Recruitment Script (see pro forma 1)

Recruitment Agreement	
Project Title:	Project No
Nature of Project	
Subject and purpose of MR Study:	
Methodology and Approach	
Fieldwork	
Location: (If online or telephone, please state this)	Duration:
Date:	Start Time:
Reimbursement	
Type: (e.g. cash or vouchers etc.)	Amount:
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 above. YES NO	
OTHER CONSENTS MAY NEED TO BE ADDED e.g. consent to install and use software	
Signature:	Name (please print)
Thank you for agreeing to participate in this market research.	

For further details about consent requirements see section E4.2 and the BHBlA's guides:

- GDPR – Legal grounds for Data Processing
- Consents for Market Research, What is required and when

Available at <https://www.bhbia.org.uk/guidelines/gdprupdates.aspx>

Pro Forma 3 – Disclosure Consent

Disclosure Consent	
THIS PRO FORMA SHOULD BE CHECKED BY THE COMPANY BEFORE USE, IT MAY NEED FURTHER AMENDMENT	
Instructions for researchers	
In the event that disclosure will be required – because the HCP (healthcare practitioner) respondent's identity is known to the commissioning pharmaceutical company and they will receive reimbursement (a payment and/or expenses) – the following consent statement should be used to ask for the HCP's permission to pass on their personal data for disclosure.	
Declaration	
In accordance with the 'ABPI Code of Practice' we must pass on certain information for public disclosure if we make a payment or pay expenses for your participation in this market research and the pharmaceutical company commissioning the market research is aware of your identity, which in this case, they/we are. If you give permission for this, the information will include your name and practice address, as well as the value of the payment and any expenses paid to you. This data will become available in 6 to 18 months' time on an ABPI-sponsored website that is open to the public [OPTIONAL USE IF APPROPRIATE and will be published on the sponsoring company's website too]. The information disclosed is required to remain in the public domain for at least 3 years.	
The purpose of disclosure is to enhance the transparency surrounding the relationships between the pharmaceutical industry and the healthcare profession.	
If you do not give your permission for this, you may still participate in the market research and your personal data will not be passed on for disclosure purposes. In this case the pharmaceutical company is obliged to publicly disclose aggregate information relating to payment and expenses.	
Your market research responses remain confidential and anonymous whether or not you consent to your name and practice address (i.e. your personal data) being used for disclosure.	
[OPTIONAL USE BY MR AGENCIES ONLY] We would prefer not to reveal the name of the healthcare/pharmaceutical company that will receive your personal data for disclosure until the end of the interview, just in case knowing this biases any responses. Is this acceptable to you or not? YES NO	
You may change your mind at any time. For more information about your rights please see the privacy notice, it is available at <privacy notice location>	
Agreement	
In line with the ABPI Code of Practice for the Pharmaceutical Industry and the UK Data Protection Act 2018, [By signing below/clicking on the box/returning this email]:	
<ul style="list-style-type: none">• I CONSENT to the transfer of my personal data [IF APPROPRIATE to XXX] for disclosure• I DO NOT consent to the transfer of my personal data	
Signature	
Signature:	Name (please print)
Other detail required eg place of work, practice address	

Pro Forma 4 – Receipt of Reimbursement

Receipt of Reimbursement	
Project Title:	Project No
Agency:	Agency Contact:
Fieldwork	
Date of receipt of reimbursement:	Start Time:
Location: (If online or telephone, please state this)	Duration:
Reimbursement	
Reimbursement Type: (e.g. cash or vouchers etc.)	Reimbursement Amount:
Declaration	
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.	
I confirm that I have received the reimbursement detailed above in appreciation for my time and contribution to the project.	
Signature	
Signature:	Name (please print)

Pro Forma 5 – Sales Aid Testing

Sales Aid Testing	
Project Details	
Project Title:	Project No
Agency:	Agency Contact:
Date of Fieldwork:	Start Time of Fieldwork:
Declaration	
I understand that: <ul style="list-style-type: none">• The exercise in which I am taking part is a sales aid study involving a 'mock' detail conducted for MR purposes only• The information that I shall see may or may not be in its final form• The information that I shall see is confidential, I will not disclose it to anyone else• Anything said within the mock detail does not constitute a commitment	
Signature	
Signature:	Name (please print)

Pro Forma 6 – Respondent Permission Allowing Client Access to Fieldwork

Respondent Permission Allowing Client Access to Viewing via Direct Observation or via Recordings of MR Fieldwork	
Project Details	
Project Title:	Project No:
Agency:	Location of Fieldwork:
Date of Fieldwork:	Start Time of Fieldwork:
Declaration	
<p>I understand that the company that commissioned this market research study</p> <p>(name of recipient organisation(s) may or may not be required will: DELETE AS APPROPRIATE</p> <ul style="list-style-type: none"> - Watch through a one way mirror (watching organisations do not need to be named) but type of organisation(s) should be specified - Listen to an audio recording at their offices (organisations listening in may or may not need to be named depending on whether audio information is considered personal data or not) - Watch a video recording at their offices (watching organisation(s) must be named but naming may be delayed until the end of the interview if viewing is not live) <p>I understand that the purpose(s) of the company having access is:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>The people in the company who will listen to or view the recordings will be in the following functions/roles:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>I understand that all those listening, watching or viewing the recording must respect the confidentiality of all information exchanged in market research interviews/groups and that no sales approaches will ever be made to me as a consequence of the company having this access.</p> <p>I understand that I can withdraw my consent at any stage.</p> <p>IF APPROPRIATE We would prefer not to reveal the name of the healthcare/pharmaceutical company until the end of the interview, just in case knowing this affects any responses. Is this acceptable to you or not? YES NO</p>	
Signature	
<p>I have read, understand and agree to the terms detailed above.</p>	
Respondent Signature:	Name (please print)
Agency Signature:	Name (please print)

For further explanatory details see section E4.2 and the BHbIA's guide Consents for Market Research, What is required and when, available at <https://www.bhbia.org.uk/guidelines/gdprupdates.aspx>

Pro Forma 7 – Client Agreement to Safeguard Confidentiality of Recordings

Client Agreement to Safeguard Confidentiality of Recordings of MR Fieldwork	
Project Details	
Project Title:	Project No:
Agency:	Location(s) of Fieldwork:
Date(s) of Fieldwork:	Start Time(s) of Fieldwork:
Commissioning Client Company:	
Declaration	
<p>On behalf of <commissioning client company name> I can confirm that the recording(s) of MR fieldwork from the above study will only be used for the following purpose(s):</p> <p>_____</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>_____</p>	
<p>On behalf of the commissioning client company I can confirm that:</p> <ul style="list-style-type: none"> • Those listening to or viewing the recording will respect the confidentiality of all information exchanged in MR interviews/groups • No sales approaches will ever be made to respondents as a consequence of the company 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 only be retained for as long as is necessary for the purposes specified, and then securely destroyed. 	
Signature	
<p>I have read, understand and agree to the terms detailed above.</p>	
Company Signature:	Name (please print)
Agency Signature:	Name (please print)

Pro Forma 8 – Observer Agreement

Observer Agreement	
Project Details	
Project Title:	Project No:
Agency:	Agency Contact:
Location of Fieldwork:	Date of Fieldwork:
	Time of Fieldwork:
Declaration	
<p>I understand that I must be familiar with and adhere to the BHBIA's Legal and Ethical Observers' Guidelines.</p> <p>Client observers must be introduced openly and honestly to respondents.</p> <p>Observers must agree to withdraw from observing if any respondent is known to them/recognised to protect the respondent's anonymity. If an observer knows they will subsequently have direct contact with a respondent, the attendee must also withdraw from observing. However, if respondents are made fully aware of the presence of an observer known to them, and give explicit consent for that individual to observe then that person may remain at the session, care should be taken that the respondents are completely comfortable if 'put on the spot' in this way.</p> <p>Observers must respect the confidentiality of all information exchanged in MR interviews/groups. You must not at any time:</p> <ul style="list-style-type: none"> • Record any respondent's personal data or record any information with the specific aim of establishing the identity of a respondent • 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 • Use information gleaned from the observation to amend or build databases. 	
Signature	
I have read, understand and agree to the terms detailed above.	
Signature:	Name (please print)



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