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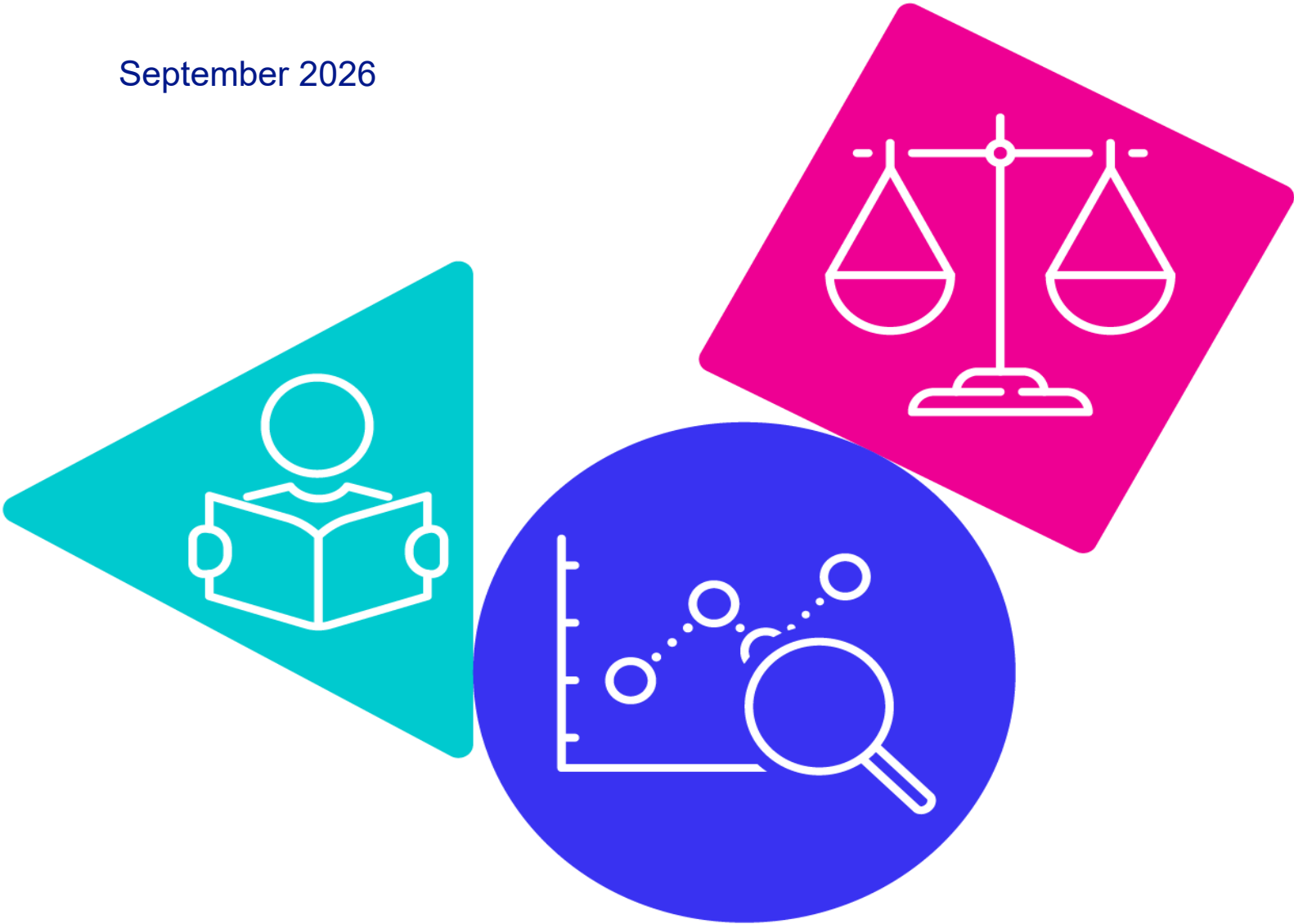
Your essential guide

Legal and Ethical Guidelines for Healthcare Market Research

September 2026



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 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, who are dedicated to providing clear guidance to all those involved in healthcare market research.

BHBIA Ethics & Compliance Committee (View Committee members here)

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 My BHBIA>My Guidelines Queries.
(Note: this ad hoc advisory service is available to full BHBIA members only).

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UPDATED LEGAL & ETHICAL GUIDELINES – CHANGES AT A GLANCE

Extended Guidance Page 11

4.2 The recruitment agreement and securing consent: Extra detail added relating to:

- automated decision-making and profiling transparency requirements;

Extended Guidance Page 17

4.5 Handling Data - International data transfers: Added clarification on the use of adequacy decisions, IDTA/UK Addendum transfer mechanisms and the need to consider transfer risk assessments when transferring personal data internationally.

Extended Guidance Page 27

7.1 - Storing and accessing respondent data - Personal data security: Added reference to documented personal data breach procedures and incident management requirements.

Extended Guidance Page 29

8.4 - Information security: Expanded guidance to include ongoing assessment of security controls and recovery arrangements following physical or technical incidents.

Revised Guidance Page 42 & 50

5 - Definition of personal data: Clarified to emphasise that an individual may be identifiable either directly or indirectly, including through the combination of information held by different parties. No change to the underlying GDPR definition.

New Guidance Page 54

Pro Forma 1 Recruitment Script Template: New optional AI consent wording added covering:

- Option 1 – To add where AI is used only on anonymised research data:
- Option 2 – To add where AI tools process personal data:

New Guidance Page 60

Pro Forma 7 Client Agreement to Safeguard Confidentiality of Recordings - Video streaming: Detail added to ensure any copy of video streaming saved on the observer's computer MUST be deleted.

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 carried out in the United Kingdom, including the Isle of Man and the Channel Islands.
- If you're working in or for a BHBIA 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 primary market research – all methodologies, project types and mediums, including but not limited to qualitative, quantitative, customer satisfaction, user experience or co-creation work carried out face to face, by telephone or online. If you need a definition of market research see section H1.

And remember, if you work in a:

- **BHBIA member company, you must follow these guidelines. It's an important condition of your membership. The same goes for the joint ABPI/BHBIA Guidance notes on collecting adverse events, product complaints and special reporting situations during market research. (We refer to these now and then in this guide.)**

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

- **ABPI member company or their affiliate, you must also adhere to the ABPI Code of Practice and you are accountable for the market research activities of your third party suppliers.** Whilst the BHBIA's guidelines take into account ABPI requirements that affect market research, additional training on the ABPI Code for third party suppliers may be required by the end client/ABPI member company.

And your connections

If you work in a BHBIA 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 fully with them.

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

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 or company 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 BHBIA. 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 an 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 L Sources, and we recommend that you familiarise yourself with that section.

?

Practical examples to illustrate the guidance have been added; please hover over this symbol or click on it to show the example. Each example takes the form of a question and answer. All of the questions and answers are listed by sub-section in order of appearance in section N.

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.**

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. You must not carry out any activities, under the guise of MR which aim to manipulate, mislead or coerce individuals.**

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 and clients with respect; you must take all reasonable steps to ensure you do not harm or disadvantage them 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.**

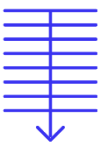
11. **You must behave ethically. You mustn't undermine or damage the reputation of healthcare or pharmaceutical MR in the UK.**

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.

Members remain responsible for ensuring that contractors, subcontractors and other third-party suppliers acting on their behalf comply with these Guidelines.

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. Please be clear and precise in the terminology you use, when referring to market research do not use the abbreviated term 'research', this could appear to imply health research rather than healthcare market research.

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.

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.

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,agency or client company will compromise your input to a competing product or organisation (e.g. because you also work with their competitor), raise this up front, and ideally before you submit the proposal.

Internal technical and organisational security measures (such as different teams, access control and privileges set on need-to-know basis, segregated networks/databases) should be in place if the organisation supports both MR and promotional activities.

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

2.3 Data protection

When preparing a proposal and considering the use of personal data within an 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 in the Privacy and Data Protection section of the website. It should be clear to the parties involved in the project which party is responsible for carrying out a DPIA (e.g. the commissioning end client or the MR agency).

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

Once the MR is commissioned you must make sure that the rights and responsibilities of all the parties involved, agencies, clients, and subcontractors, as data controllers or data processors are governed by a written contract or data protection agreement.

2.4 Diversity, Equity and Inclusion

When writing a proposal, you should address Diversity, Equity & Inclusion in relation to your MR project, by
(a) considering who needs to be included in your sample to reflect the population of respondents being researched,
(b) how to make your research accessible and inclusive,
(c) considering the purpose for which you are collecting information in relation to this and
(d) how this might impact your chosen methodology and the feasibility of the project.

The MRS has some guidance available at https://www.mrs.org.uk/resources/diversity-and-inclusion-guides-for-clients

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 the 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 25.4.

3.3 Sample source

You must verify the provenance of any sample sources. It is your responsibility to satisfy yourself about the integrity of the data supplied to you. You should make appropriate enquiries and checks e.g. about the data source or usage rights.

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 including the way in which they can expect to be contacted e.g. email and/or telephone**
- **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**

The BHBIA 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 remuneration. 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 remuneration 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 an MR screening interview, the information above must be delivered when that personal data is collected, i.e. at recruitment.**
- **If the personal data are not obtained directly from the individual, e.g. via digital listening or desk research, the information above must be delivered:**
  - **If the data are to be used to communicate with an individual, then at the latest at first communication with the data subject**
  - **If the data are to be shared/disclosed with another organisation, at the latest when the personal data are first disclosed.**

  The information must be delivered within a reasonable timeframe (one month at the most) of the personal data being obtained. This provision is subject to certain exemptions cited in Article 14 of the UK GDPR.

  It is possible to 'layer' the information so the consent is collected when it is relevant with the aim not to overwhelm the data subject. Consent to participate, recording and/or observation could for instance be collected during the initial recruitment interaction with the data subject (alongside informing them about their right to withdraw), whereas more detailed information about how the data subject is able to exercise their right access that personal data and withdraw consent for its processing could be provided in a separate document such as a privacy policy available as a separate document (e.g. via email) or online.

- 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.

  The nature of the service to be provided by respondents must be clear and it must be immediately apparent that the purpose is market research. BHBIA, MRS and ABPI requirements mean the agreement/consent must include:
  - **subject and purpose of the MR study**
  - **methodology and approach, including, the medium for the MR and the means by which they would be contacted for recruitment e.g. telephone and/or email, recruitment means must be clear to panel members too**
  - **location and duration of fieldwork**
  - **date and time of fieldwork**
  - **reimbursement offered – both the nature and the rate of remuneration**
  - **adverse event (AE), product complaint (PC) and special reporting situation (SRS) 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 e.g. the commissioning client company**
  - **recipients of their personal data, this will require you to name any other organisation the personal data is being transferred to e.g. the commissioning client company**
  - **why you want their data (purpose) and what you will do with it (types of processing activity) including if and how viewing or recording will take place and who will have access to live or recorded information**
  - **if the data is not obtained directly from the data subject the categories of personal data**
  - **their right to withdraw consent at any time**
  - **Where automated decision-making or profiling is used, individuals must be informed of its existence, the logic involved where appropriate, and the potential consequences for them. Individuals are entitled to understand how profiling information has been derived and to request correction of inaccurate information. Organisations remain responsible for ensuring that any profiling process is fair, lawful, transparent and appropriately validated.**

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

Extended Guidance
Page 4

- **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 1 and 2 for a template for this. Whilst the recruitment script will need to be tailored to the project and the medium (e.g. telephone, online), the recruitment 'conversation' must be based upon a script that is clear and comprehensive. It must be made immediately clear who is making contact and why. Ideally it should also be agreed by all parties involved and approved by the end client.

- Naming the data controller, source and recipients of personal data

Data protection law 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

The ABPI Code of Practice 2024 (clause 5.6) does not require that MR materials include the name of the end client (unless there is a legal requirement) but the material must state that it is commissioned by a pharmaceutical company.

- 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 this must be followed up with a written contract or agreement as per ABPI Code of Practice**
- 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 e.g. 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 data protection guides available in the **Privacy & Data Protection** section of the BHBIA website:

- Lawful Bases for Processing Personal Data
- Consents for Market Research - What is required and when

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 (remuneration and/or expenses) IF the identities of individuals (HCPs or non-HCPs, healthcare or patient organisations) who take part in MR are known to the commissioning pharmaceutical company.

The extension of disclosure to cover non-HCPs (if their identity is known to the commissioning pharmaceutical company) was introduced in the 2021 ABPI Code of Practice update and took effect for payments made in 2022.

For HCPs disclosure should be on a named basis if possible; whereas disclosure of non-HCP payments may be aggregated.

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 or in kind, made in connection with the development or sale of medicines. Disclosure requirements apply whether the individuals or organisations are paid directly or indirectly via an agency, recruiter or interviewer. Indirect transfers of value include those paid to an employer, organisation or to companies or charities. It applies to any product made available on prescription (whether prescription bound or not).

Definitions of HCP, non-HCP, healthcare and patient organisation can be found in the section K, Key Terminology.

- Processing personal data for disclosure purposes

Individuals whose identity is or will become known to the commissioning pharmaceutical company must be told before fieldwork starts (generally at recruitment) how their personal data will be used for disclosure.

A lawful basis for any disclosure related data processing must be in place. This might be:

(a) Legitimate interests
The ABPI encourages the use of 'legitimate interests' as the lawful basis for processing individuals' personal data for the purposes of disclosure, in the interests of ethical and transparent collaboration; stating in its resource Disclosure UK | What is Legitimate Interests?' (https://www.abpi.org.uk/publications/what-is-legitimate-interests/):

> *Under 'Legitimate Interests' a company asserts their transparency commitments over the data rights of the individual HCP. To reach that conclusion, a company must first consider why it wants to deal with the data in this way, if there are other means of achieving the same result, and if, on balance, the legitimate interests of the company in making this data publicly available should override the individual HCP's own interests.*
>
> *In practice, this means **a company does not ask the HCP for permission to publish their name and practice address with the value received on Disclosure UK**. Whilst no longer asking for formal consent, the company has a responsibility to be clear about their intentions with the HCP and must allow individuals to exercise their right to raise objections.*

Please note, use of legitimate interests as a lawful basis should be based on a legitimate interests assessment (LIA). This is a risk assessment that will document the data controller's balancing of its legitimate interests against the individual data rights of the HCPs. Please see the document 'Lawful Bases for Processing of Personal Data' available in the **Privacy & Data Protection** section of the BHBIA website for more details.

(b) Consent
Companies may consider using consent as their lawful basis and if it is used it must be clear to individuals:

- **why the use of their personal data is being requested**
- **how it will be used, this includes who it will be given to**
- **they have the 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. Please see the document 'Lawful Bases for Processing of Personal Data' available in the **Privacy & Data Protection** section of the BHBIA website for more details.

- Disclosure notification

  As disclosure reporting is a separate processing operation (to the MR), consent for this may be secured at the end of the interview.

  The BHBIA has provided a pro forma for disclosure notification – see section M Pro Forma 3.

  If the lawful basis is:
  - legitimate interests and an individual objects to this, the disclosing end commissioning client, as the ABPI member and data controller, must decide how to deal with this.
  - consent and an 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.

  Some companies may already have contractual arrangements in place with HCPs that include disclosure so no further agreement is required just a reminder that these arrangements will apply.

- Non-HCPs (whose identity is or will become known to the commissioning pharmaceutical company)

  As it is not necessary to disclose the individual transfers of value made to non-HCP's, only the aggregated total for groups of non-HCP individuals e.g. the patient respondents within a market research survey, there is no requirement to collect their personal data for disclosure purposes.

- When disclosure is not required

  If an individual'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 individuals to the pharmaceutical company but a 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 reporter details – EFPIA have confirmed this in their FAQs or
  - when viewing fieldwork a pharmaceutical company observer happens to recognise and can identify what should have been an unknown respondent

  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 respondents for interview, unless everyone listed is interviewed (a census), the identity of those actually interviewed won't be known and so disclosure isn't likely to be required. ?

- What must be disclosed

  For individual named HCPs (that have given their consent for their personal data to be used) or HCOs:
  - Name, ID (if appropriate) and address (HCP and organisations only)
  - Fee for service and consultancy i.e. the market research remuneration
  - Related expenses such as travel

  Where an individual's information cannot be disclosed for legal reasons, i.e. when an HCP refuses consent for the use of their personal data for disclosure, the following must be provided:
  - Aggregate transfers of value i.e. the remuneration and expenses (separate totals) for MR respondents
  - Number of recipients (separate totals for fees and expenses required)
  - % of all recipients that they represent

  The ABPI has developed a template showing exactly what data must be provided, this is available on the PMCPA website: Publications

Only aggregated information is required for non-HCP respondents, this must include:
- the total number of members of the public involved
- the total amount paid to members of the public per calendar year i.e. the aggregate amount
- a description of the types of services provided
- a breakdown of the total payments to each group of individuals (e.g. patients, carers), there is no requirement to disclose personal data of non-HCPs

- How this information must be disclosed

  Pharmaceutical companies must disclose the information through a central ABPI-sponsored online platform that is 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 remuneration/ expenses were paid.

- Record keeping

  Respondents' consent or refusal must be recorded.

  Agencies must keep records of the disclosure information to pass to the pharmaceutical company. 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 should agree with their MR agencies a reporting schedule for disclosure information. The BHBIA 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

  A payment to an individual representing a patient organisation should be disclosed as a payment to that patient organisation. The information to be disclosed must include the total amount paid per patient organisation over the reporting period and a description of the services provided. Information about healthcare organisations (HCOs) is not considered personal data therefore a lawful basis is not required to publish organisations' names and addresses on Disclosure UK. The ABPI expects all business intelligence related transfers of value made to HCOs to be published individually.

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 lawful 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.

  Before agreeing to receive a customer client list or database (e.g. a list of doctors visited by sales representatives), you should ask the list supplier (the data controller for the list) to confirm that they have the right to share the list for MR purposes, this requirement could be covered in the contact/data processing agreement. It is your responsibility to satisfy yourself about the integrity of the data supplied to you. You should make appropriate enquiries and checks e.g. about the data source or usage rights. **The client company must have a lawful basis for the 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 assessment (LIA) and determined that it is in their legitimate interests to do this. For further details about LIAs see the BHBIA's Lawful Bases for Processing Personal Data and the Sharing Personal Data guides, available in the **Privacy & Data Protection** section of the BHBIA website.

  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 end client company if they provided the names even if the names are supplied via a third party.

  However, 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, transferring 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 transfer and 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 emails and other documents received from respondents agreeing to (or restricting) the use of or access to their personal information.

- Sharing personal data

  This includes the disclosure of personal data by transmission, dissemination or otherwise making it available. As well as making sure that you have a lawful basis for sharing personal data, you should be aware of laws other than data protection law that could constrain your ability to share data e.g. copyright restrictions. Accountability obligations mean that if you are involved in a data sharing arrangement, you are responsible for your compliance with the UK GDPR or DPA 2018, and you must be able to demonstrate that compliance.

  For further information on safe data sharing and the ICO's Data Sharing Code of Practice please see the BHBIA's 'Sharing Personal Data' guide available on the BHBIA website.

- Sharing personal data securely

  For information and tips on sharing personal data securely please see the BHBIA's guides to 'New technologies: due diligence and online security in Business Intelligence (BI) and Data Analytics (DA)' available in the **Privacy & Data Protection** section of the BHBIA website.

- 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 (to a third country) unless there are adequate data protection measures in place. The Information Commissioner's Office provides a list of countries providing adequate protection for UK data subjects in connection with the processing of their personal data: International data transfers | ICO

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  Where personal data is transferred outside the UK to a country that is not covered by an adequacy decision, appropriate transfer mechanisms must be implemented. These may include the International Data Transfer Agreement (IDTA) or the UK Addendum to the EU Standard Contractual Clauses, together with any required transfer risk assessment.

  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 the ICO International Data Transfer Agreement
  - Implementing binding corporate rules (BCRs) 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.

- 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 e.g. 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 commissioning company identity

  You must reveal the commissioning company's name – you must 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 an 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 remuneration is offered, respondents must be clearly informed of the following:
  - **who will administer the remuneration**
  - **what the incentive will be**
  - **when the participant will receive the remuneration/incentive**
  - **whether any conditions are attached e.g. completion of a specific task or passing of quality control checks**

The remuneration to be paid must be entirely clear and 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. If payments are changed the client should be kept informed of this.

- 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 remuneration could be viewed as inappropriate or excessive it could be viewed as a bribe. The ABPI Code of Practice 2024 (clause 24.2,) advises that the "remuneration for the services must be reasonable and reflect the fair market value of the services provided". A useful criterion in determining whether the remuneration is acceptable is to apply the question 'would you and your company be willing to have the remuneration generally known?' The impression that is created by the remuneration 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 need the client's permission and approval of the content to do so.

  Setting a fixed ceiling or cap on remuneration 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 remuneration should be reasonable and in line with fair market value agreed with commissioning company/end client. Fair market value will depend on a number of elements including kind of activity, amount of time invested and experience and skills of the people involved.

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

  UK affiliates should be involved in setting and approving remuneration 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 remuneration 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 remuneration.

  The BHBIA has produced a Guideline for Remuneration Within Market Research. Members are encouraged to use this guide to reduce problematic pressures on respondent payments based on FMVs.

- 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 an 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:

- Quizzes

  The 2024 ABPI Code of Practice states that:

  Clause 10.7: Events/Meetings and Hospitality
  Quizzes which are intended to gauge attendees' understanding of the subject matter of a meeting are acceptable provided that such quizzes are non-promotional and genuine tests of skill or knowledge; they must respect the professional standing or otherwise of the audience and no prizes can be offered.

  Clause 26.3 Relations with the Public, Including Patients and Journalists
  Companies cannot run or sponsor competitions or quizzes for patients if prizes are offered.

  Market research exercises should be very clearly distinguished from quizzes and not described as quizzes.

- Panel members

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

  Consent to maintain inactive panel members' personal data on file should be refreshed at regular intervals. There is no set time limit for consent. How long it lasts will depend on the context. You should review and refresh consent as appropriate.

- 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 commissioning company's 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's Questionnaire Design Guidelines.

- 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 BHBIA'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 Reversing the decline in HCP participation - full report | BHBIA

For practical guidance on how to implement better screening practice, the BHBIA Fieldwork Forum have created a Screener Design and Best Practice Guide – see details at: Screener Design & Best Practice Guide | BHBIA

- 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 3.6. 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.

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

  Generic names that either alone or when presented alongside other information that could identify an individual medicine should be treated with the same caution as brand names – see guidance above.

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. A topic may also be sensitive to a group for cultural, religious or political reasons.

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 gender interviewers, or offer the choice of a same gender interviewer.

It is important to make sure that respondents can easily and comfortably provide a response if asked about sex and/or gender. It is advisable to:

- Ask for this information only if it is necessary
- Distinguish between sex and gender e.g. sex at birth and current gender identity and provide a free text response option and a 'prefer not to say' option.

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

– Guidance Note on Collecting Data on Sex and Gender, July 2020
– Guidance Note on Researching Age Bands for Over 65s, June 2016

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:
  – **materials or messages – promotional or educational, draft or finalised, pre or post launch**
  – **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.:

  Please note that the information shown contains clinical data that hasn't been validated.

  Assuming the product performs as described....

  Please note that what you're looking at is giving information about a medicine that's still being developed. So it contains some assumptions.

  The ABPI Code of Practice (Clause 6 Information, claims, comparisons and disparagement) 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 either 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

- MR testing of promotional messages or materials

  MR testing of promotional messages or materials (e.g. to assess reaction to them before or after launch) is allowable – there are no laws or industry regulations (healthcare or MR) that prohibit it. However it is essential that the reasons for their use are clearly and directly linked to bona fide MR objectives and the work is carried out in compliance with the BHBIA's Guidelines. It would also be necessary to make sure respondents:

  - Understand the nature of the MR and are advised in advance that they will be asked about their reactions to promotional materials/messages and
  - Are protected from disguised promotion (see sections E5.2 and H4)

- Examination of MR Material

The ABPI Code of Practice states that MR material should be examined by the commissioning client company by an appropriately qualified person (not necessarily a signatory) to ensure that it does not contravene the ABPI Code or relevant statutory requirements (certification is not required), see clause 8.3, supplementary information. 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 BHBIA provides online training specifically for non MR personnel involved in reviewing MR materials – see the online training section in the **Online Training** section of the BHBIA 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 or devices 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 needs to approve the respondent taking it.
    https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/
  - **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.**
    https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/good-clinical-practice/

  - **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.**

  When handling any device that could be harmful, respondents should be trained and must be supervised, with handling kept to a minimum. Training may not be appropriate when it would undermine the research findings e.g. when the purpose of the testing is to assess handling amongst those new to a device, although participants must be given all the information and support they would receive in the real-world situation. We also advise that all device MR work should be carefully risk assessed before it takes place and the end client's medical department involved.

  If respondents include patients, the patients selected should fit the criteria for those who would be prescribed the product or who are already using a similar device.

  Devices must not be left with the respondent and must be collected and returned to the client at the end of the MR or securely destroyed.

- 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 market 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

It is the responsibility of research practitioners to keep abreast of any legislation which could affect market research. We also strongly advise that you make sure you are aware of and follow the latest government guidance. The guidance the BHBIA provide is in addition to any mandatory government requirements in place.

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) medicine or device, whether or not there's a proven link to the medicine or device.

Researchers are not responsible for determining seriousness, severity, expectedness or causality. Where there is doubt as to whether information constitutes an AE, PC or SRS, it must be forwarded in accordance with the ABPI/BHBIA AE Guidance.

For the full reporting requirements see the latest: **ABPI/BHBIA Guidance notes on collecting adverse events, product complaints and special reporting situations during market research**.

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, listening in 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 key opinion leader (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/listening in 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, listened to or recorded**
  - **who will have access to the data – the organisation type and the types of people viewing/listening in, the organisation may need to be named depending how viewing takes place or whether the voice is considered personal data (see Actions for different viewing and recording methods involving the end client below)**
  - **why i.e. 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. So, even if there is no transfer of personal data to the end client, in the interests of transparency, market research regulations require that respondents are not watched or recorded without their consent.

  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, listening in or audio/video recording before this starts, i.e. at recruitment.

If non-anonymised viewing, listening in or recording via video-relay or streaming takes place you must name recipients of the personal data whatever the status of the recipients (e.g. 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 or listen to 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. For further information please see the BHBIA's guide to 'New technologies: due diligence and online security in Business Intelligence (BI) and Data Analytics (DA)' available in the **Privacy & Data Protection** section of the BHBIA website.

  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 fieldwork. You must remove their contribution from the analysis and reporting if this is requested.

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.

  Respondent personal data (e.g. full names, job title and place of work) must not be available to observers unless appropriate consent is obtained from the respondent.

- Observers' responsibilities

  You must obtain agreement from observers to abide by the following:
  - **To withdraw from observing/listening in 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/listening in (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 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.

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  Organisations processing personal data must have documented procedures for identifying, assessing, recording and responding to personal data breaches, including determining when notification to affected individuals or the relevant supervisory authority is required.

- 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 market 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 market 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, sample design and selection procedure, 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.

In addition, researchers must make available if required, the method of data collection and any instruments used, any data cleaning, weighting or post-field adjustments applied, any substantive limitations affecting the validity of the findings.

- 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, including if results are to be sent to MR participants.

  You must check any materials clients have prepared to ensure the market 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 (AEs), product complaints (PCs) and special reporting situations (SRSs) forwarded to the commissioning company so that reconciliation can be performed as required.
See the latest **ABPI/BHBIA Guidance notes on collecting adverse events, product complaints and special reporting situations during market research** 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**

There is no set time limit for consent. How long it lasts will depend on the context. You should review and refresh consent as appropriate.

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.

All parties involved in a MR project must be aware of their obligations regarding the collection, transfer, retention, security, disposal and destruction of data. 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.

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Organisations must regularly test, assess and evaluate the effectiveness of their technical and organisational security measures, where appropriate. Reviews may include security audits, testing of controls, staff training, access reviews and evaluation of disaster recovery arrangements.

Appropriate contingency and disaster recovery arrangements should be maintained to allow restoration of access to personal data following a physical or technical incident.

For further information please see the BHBIA's guide to Data Security available at Data Security including Breaches and International Transfers | BHBIA

8.5 Further processing of data for a secondary purpose

You must make sure that there is a lawful basis for the further processing of data for a secondary purpose. This may include consideration of:

- Links between the original and proposed new purpose/s
- The context in which the data was originally collected (in particular the relationship between respondents and the original data collector)
- The consequences of the proposed secondary processing
- The existence of safeguards.

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 market research, and could have cause for complaint.

2 Vulnerable respondents

You must take reasonable steps to assess, identify and consider the particular needs of vulnerable people involved in MR. Vulnerable individuals must be capable of making informed decisions and not unfairly pressured to cooperate.

- Defining vulnerable

  This refers to respondents who could be more susceptible than normal to physical or mental stress brought on by the market research process. This could be due to their age, or physical or mental health. It would also include individuals whose capacity to make voluntary and informed decisions is limited or compromised.

  As the MRS point out in their guidance, it is important to be aware that vulnerability is a complex and dynamic state that can affect anyone at any time for many different reasons. For this reason, is important not to make assumptions about which conditions might or might not make a patient vulnerable.

- Design considerations

  - Make it clear that questions will be limited to those that respondents are comfortable to answer
  - Reassure respondents not just about privacy but about the importance placed on their well-being too
  - Provide advance warning that some of the questions may be considered sensitive
  - Ask respondents to say if any question feels inappropriate
  - Make it clear that respondents are not required to respond to anything they do not feel comfortable with

- 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?
  - Has the potential impact of the MR project upon the individual been assessed?
  - Should a carer be present or on hand (if they have one)?
  - Is extra time needed?
  - Are specially trained interviewers required?

- Special planning

  You should consider some special conditions and contingency planning for these interviews. For instance:
  - Send email invites before recruitment calls are made
  - Make it very clear what the precise focus of the project is and what type of information will be sought
  - Same gender interviewers may be appropriate
  - Provide breaks
  - Offer to postpone or cancel the interview
  - Provide helpline numbers/website addresses, charity details or any other supportive information and/or with their explicit consent offer to put them in touch with support services.
  - Carry out a data protection impact assessment (assuming data processing is being undertaken)

The MRS's 'Best Practice Guide on Research Participant Vulnerability, August 2022 may also be helpful to you, this is available at MRS Researching Vulnerable Participants 2022.pdf

Remember difficult interviews held with vulnerable respondents may be distressing for interviewers too, so they may need support themselves.

3 Children and young people

You may wish to interview patients or sufferers who are under 18 years of age. See the *MRS Guideline: Conducting data collection activities with children February 2020* for the full rules. **You must take special care when considering whether to involve children in MR. The project design must take into account their age and level of understanding.**

- 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 which is recommended when there isn't a specific national definition).

  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 market 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 market 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.

- Age appropriate design

  This means that the age range of your audience and the different needs of children at different ages and stages of development should underpin the design of your data collection activity.

  For further detail, please see the MRS's Guidance: ICO Age Appropriate Design Code; MRS Guide to ICO Age Appropriate Design Code.pdf

  This Code is a data protection code of practice for online services likely to be accessed by children. The Code is relevant for researchers e.g. online product testing with children. It is a statutory code and organisations need to conform.

- Remuneration

  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

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 being taken by the respondent on a mobile or smartphone, 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**

  Your privacy notice should make clear what permissions the app will require to function (e.g.: access to camera, gallery image, contacts, browser history, etc.), the cookies placed by the app, data retention period/policy; and your commitment to continue notifying those who have the app installed about changes to the notice.

  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.

- Chat and instant messaging apps

  The terms and conditions set by the App provider must be followed, e.g. if WhatsApp is to be used, the conditions set by WhatsApp LLC and the Facebook companies must be followed.

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)

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 (i.e. their identity can be established).

- Good practice
  - Clearly inform participants in writing of the exact nature of the market 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

- Self-recording

  Remind participants self-recording that any recording, unless required for the study, should not include any other individuals but themselves. Provide:
  - Guidance on the positioning of the camera, use of headphones and/or audio/volume settings.
  - Advance warning to consider indoor (e.g., family members/people living in the same house) and outdoor (capturing passing members of the public) scenarios.
  - If there were accidental intruders in the footage provided, researchers are unlikely to have a lawful basis to process this content and shall redact it from the files at the earliest opportunity, and at the very least before further processing or transfer to another party.
  - Have processes in place to review any self-recorded data to remove/anonymise any personal data from other individuals (unless required for the MR).
  - A reminder that the MR is confidential and recordings should only be shared with the commissioning party e.g. the MR or the fieldwork agency.

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 email
- 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 emails (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 email 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 email 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 make a privacy policy statement/privacy notice available to respondents, clients, suppliers, website users etc...
This should be easy to find (e.g. via an obvious link on the website or within a survey invitation), 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:
Create your own privacy notice | ICO

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.

- Apps

  For guidelines on the use of apps please see Apps in section G2.

- 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 email 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 e.g. participants have given consent for their personal data to be used for the purpose(s) that you

intend to use it. Remember if you are processing an individual's own health data their explicit consent will be required (as this is 'special category' personal data. 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 having a lawful basis for doing this.
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 e.g. 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.

Do remember data protection requirements (e.g. data minimisation etc.) apply to personal data obtained indirectly e.g. via digital listening, as well as that obtained directly from those actively engaged in MR.

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 market 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. Some platforms are very prescriptive about the way data from their site is replicated and their requirements are frequently updated.

- Reporting adverse events, product complaints and special reporting situations

As with all forms of MR, appropriate AE/PC/SRS reporting processes must be put into place for MR using social media. In addition to the ABPI/BHBIA's Guidance notes on collecting adverse events, product complaints and special reporting situations during market research it may be helpful to consult the ABPI's *Guidance notes on the management of safety information and product complaints from digital activities* available online:

https://www.abpi.org.uk/publications/guidance-notes-on-the-management-of-safety-information-and-product-complaints-from-digital-activities/

- Use of Social Media

  Care must be taken when you are conducting market research on behalf of a Pharmaceutical Company and utilising social media such as Facebook, LinkedIn, Instagram e.g., for recruitment. As you are working on behalf of a Pharma Company, they are responsible for anything you post. Therefore, you need to ensure that anything you post on social media has been approved by the company. Ensure that comments on posts are disabled to remove the need to monitor for adverse events being reported.

6 Using sales representatives to gather MR information

Historically, sales representatives (reps) have sometimes been involved in gathering information that has been referred to as MR data. We strongly advise against this because:

- a representative's role is promotional and they represent the company, so they cannot be considered unbiased
- reps aren't professionally trained interviewers, and may not be familiar with professional MR codes and legal requirements
- the market research may be more vulnerable to an accusation of disguised promotion
- respondent anonymity and confidentiality are compromised
- respondents are less likely to feedback openly and accurately
- reps cannot handle reimbursements

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 market 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 company commissioning the research 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)

The term 'market research' is used throughout the Guidelines but it is recognised that market research work may be carried out by teams with a variety of titles and functions such as business/commercial intelligence, consumer/market insight, marketing/data analytics, customer science. Market research is used with these Guidelines as an 'umbrella' term that describes work meeting the definition below.

Market research, whatever it is called, whoever commissions it and whatever approach is used, has four key characteristics:

1. Its purpose is to gain insight or support decision making by generating understanding and knowledge.
2. It involves the systematic collection, analysis, interpretation and use of information about individuals, organisations or market places using the information gathering and analytical methods and techniques of the applied social, behavioural and data sciences, statistical principles and theory. Information (data) is obtained from specific samples and the findings extrapolated to the population as a whole. MR is scientifically conducted.
3. MR has no interest in the individual identity of respondents; respondents have to be offered confidentiality and anonymity even if we then ask them to waive it e.g. so that we can view non-anonymised fieldwork.
4. It does not result in direct action relating to individuals or organisations participating in it (except following up adverse events when permitted). MR is not a commercial communication or a selling opportunity.

As we have said we use the market research as an umbrella term and it includes 'marketing' research; traditionally marketing research has been understood to cover customers, products, competitors, channels and suppliers, whereas market research is narrower focusing on investigating markets, we do not draw this distinction.

In addition, with the broadening of MR options over the years in terms of new methods (e.g. digital listening, behavioural economics, usability testing, ethnographic work, co-creation), new mediums (e.g. mobile devices) and new data sources (e.g. social media), it is important to be clear that the BHBIA's Guidelines apply to both traditional and the newer or non-traditional options.

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 a company (and are under contract to the company). They often provide expert advice on emerging products or developments and the advisors identities are usually known to the company. If the advisory board is recruited and operated as market research meeting the definition above, then it is market research and MR compliance requirements would apply.

Please be clear and precise in the terminology you use, when referring to market research, do not use the abbreviated term 'research', this could appear to imply health research rather than healthcare market research.

You should also be aware that on the BHBIA website, within the section, there is a '*WHAT IS MARKET RESEARCH?' page:* What is Market Research? | BHBIA

> *This resource section is designed for people who do not work in healthcare business intelligence, but who may need to know more about the work we do in our industry, for example because they have been invited by one of our member companies to take part in a market project. The following resources are available:*
>
> – *Information for Healthcare Professionals:*
> Market Research: Information for Healthcare Professionals | BHBIA
>
> – *Information for the General Public:*
> Market Research: Information for the General Public | BHBIA

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 commissioning company

This reflects the MRS's *Regulations for Using Research Techniques for Non-Research Purposes June 2020.*

- 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: Using research techniques for non-research purposes
https://www.mrs.org.uk/pdf/MRS%20Regulations%20Using%20Research%20Techniques%20for%20Non-Research%20Purposes%202020.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 Governance arrangements for research ethics committees.

The 'Governance arrangements for research ethics committees: 2020 edition' published by the Health & Care Research Wales, Health & Social Care Northern Ireland, NHS Health Research Authority England, NHS Research Scotland, state that:

2.3.15 Market research may be undertaken by professional market researchers, e.g. for public health research or on behalf of pharmaceutical or medical device companies. Where such research is conducted by professional market researchers in accordance with the principles set out in the Market Research Society Code of Conduct or 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 Acts.

https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/GAfREC_Final_v2.1_July_2021_Final.pdf

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. https://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2022.pdf They also provide a decision support tool to help determine whether a study should be classified as 'research' or not. http://www.hra-decisiontools.org.uk/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 (section1.3) available on the EphMRA website https://www.ephmra.org/sites/default/files/2023-09/2023%20EPHMRA%20Code%20of%20Conduct%2025.9.23.pdf

EphMRA point to the following key distinction

"Non-interventional research studies involve the collection of 'additional data post-authorisation. Such post-authorisation measures may be aimed at collecting data to enable assessment of the safety or efficacy of medicinal products in the post-approval setting.

Market Research is carried out for a commercial purpose i.e. to investigate customer behaviours and market opportunities, to inform business decision making, clinical endpoints are not needed for market research."

A guide on What is Research Ethics Committee Approval and when is it needed? can be found here: New Guidance - What is Research Ethics Committee Approval and When is it Needed? | BHBIA

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 remuneration 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, health data and data processing

Revised Guidance
Page 4

The GDPR defines personal data as

> "any information, either alone or in combination with other 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 falls within the scope of the data protection requirements. If you have the means to reverse the pseudonymisation within your organisation, the pseudonymised data must be treated as personal data.

Personal data includes electronic, manual and recorded data held in alphabetical, numerical, graphical, photographical 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.

- Health data

  Under the UK GDPR, 'data concerning health' means personal data related to the physical or mental health of a natural person. This definition includes the provision of healthcare services, which reveal information about a person's health status. The Information Commissioner's Office (ICO) has confirmed that 'data concerning health' can also relate to healthy individuals, and includes data from medical devices and fitness trackers (e.g., the number of steps taken by the user or athletic performance). Data such as appointment details, reminders and invoices may also constitute health data if it reveals or could in combination with other data reveal information about a person's health through 'reasonable inference'.

  Additionally, the UK GDPR uses the concepts of 'genetic data' and 'biometric data'. 'Genetic data' means personal data relating to the inherited or acquired genetic characteristics of a natural person that give unique information about the physiology or the health of that natural person. Such data results, in particular, from an

analysis of a biological sample from the natural person in question. 'Biometric data' means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person. Biometric data is an open category and can include a broad set of identifiers such as DNA matching, iris and retina recognition, facial recognition, and fingerprint and voice recognition.

Source: https://www.lexology.com/library/detail.aspx?g=bef460fb-cde1-4705-a81b-e5269d82dc6b&utm_source=Lexology+Daily+Newsfeed&utm_medium=HTML+email+-+Body+-+General+section&utm_campaign=Lexology+subscriber+daily+feed&utm_content=Lexology+Daily+Newsfeed+2021-07-20&utm_term=

6 Adverse events, product complaints and special reporting situations

- 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.

- 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 (SRS)

  In some specific situations, information must be collected and reported even where there is no associated adverse event. Examples include pregnancy exposure, breast-feeding exposure, overdose, misuse, abuse, medication errors, lack of therapeutic efficacy, off-label use and withdrawal syndrome. Additional company-specific requirements may also apply.

For more information on all of these, see the latest **ABPI/BHBIA Guidance notes on collecting adverse events, product complaints and special reporting situations during market research.**

7 Informed consent

'Informed consent is the process by which research participants voluntarily confirm their willingness to take part in a particular project, after having been informed of all aspects of a project that are relevant to their decision to participate.'
MRS GDPR In Brief (No. 5), Informed Consent

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 UK 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 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.
  Please see the document 'Lawful Bases for Processing of Personal Data' available in the **Privacy & Data Protection** section of the BHBIA website for more details.

- 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 e.g. sample sizes are small and made up of opinion leaders or when other information can easily be added.

- Patients

  Under the UK GDPR/2018 DPA, 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.

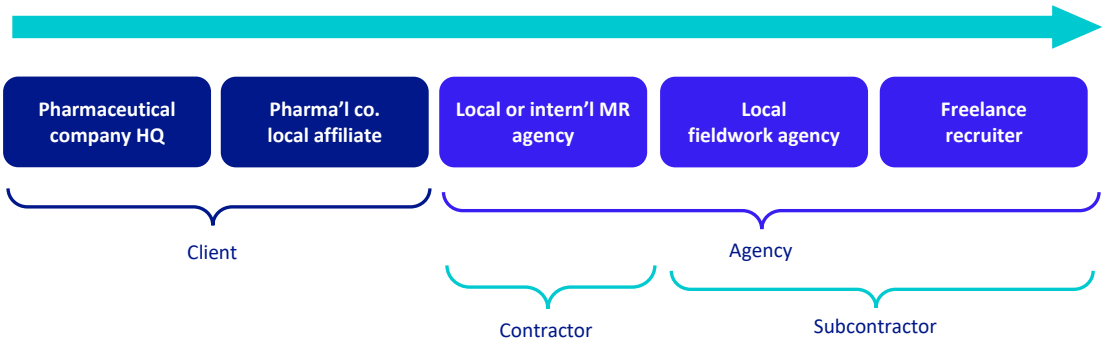
- Client Companies

  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 e.g. 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 an 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

FOR DETAILED ADVICE AND EXPLANATIONS OF DATA PROCESSING REQUIREMENTS PLEASE SEE THE **PRIVACY & DATA PROTECTION** SECTION ON THE BHBIA'S WEBSITE.

1 Requirements

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

- Responsibilities

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

  Data protection requirements (Article 5(1)) state that personal data shall be:

  > "(a) processed lawfully, fairly and in a transparent manner in relation to individuals ('lawfulness, fairness and transparency');
  >
  > (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 ('purpose limitation');
  >
  > (c) adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation');
  >
  > (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 ('accuracy');
  >
  > (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 ('storage limitation');
  >
  > (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 ('integrity and confidentiality')."

  Article 5(2) adds that: "The controller shall be responsible for, and be able to demonstrate compliance with, paragraph 1 ('accountability')."

- 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.

  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;
- assist the controller in meeting its data protection 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 obligations, and tell the controller immediately if it is asked to do something infringing data protection law.

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/for-organisations/uk-gdpr-guidance-and-resources/accountability-and-governance/contracts-and-liabilities-between-controllers-and-processors-multi/

- 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 some MR suppliers. For further information about appointment of DPOs see the BHBIA's guide Data Protection Officer | BHBIA

J COMPLAINTS POLICY

The BHBIA can only engage with complaints that relate to either:

1. **A potential breach of BHBIA Guidelines[1] committed by a current BHBIA member[2] organisation / individual, or their subcontractor when conducting business intelligence[3] activities in the UK[4]**
2. **A service provided by the BHBIA - e.g. an event or resource - or an interaction with one of the BHBIA team**

The complaints policy is open to any individual or organisation who has a complaint which meets the above criteria (referred to hereafter as the 'complainant').

To help us respond to your complaint:

- Please provide us with as many specific details as possible about your concerns – i.e. the exact nature of the complaint(s) and the details of the individual/organisation you are complaining about (referred to hereafter as the 'complainee') – for example, organisation name / individual name / project reference no. etc. as applicable.
- Unless specific circumstances make this difficult, this information will be required in writing.
- Complaints will be initially investigated by the BHBIA's administrative staff and contracted independent executive support team, including as appropriate, the BHBIA's Officer(s) and/or the BHBIA's Ethics Advisor. If it is necessary to seek wider opinions, it is likely that appropriate members of the BHBIA Board or Ethics & Compliance Committee will become involved.
- In the interests of transparency, and to give the complainee a fair opportunity to respond to the specific issues, we will normally only consider a complaint if you consent to your identity being made known to the complainee; however there may be exceptions to this and if you have a clear justification for remaining anonymous we will consider it.
- Beyond the above, your identity will be kept confidential and only shared with members of the contracted independent support team directly involved in investigating the complaint. Likewise, the identity of the complainee will also be kept confidential.
- Should the investigating team be extended to Board or ECC members, identifying details of the complaint, including the individuals and organisations involved (both complainant and complainee) will be anonymised.
- Any complainant will be expected to attempt to resolve the matter with the complainee before approaching the BHBIA. We may ask you to satisfy us that you have taken all reasonable steps to try to do this, before coming to us
- We will not usually be able to engage in discussions about a complaint if there are legal proceedings contemplated or ongoing in respect of the matter
- Please ensure that you make it clear to us whether you are letting us know about a situation for information purposes only, or whether you are specifically asking us to investigate a complaint

Please note that unless there are exceptional circumstances we cannot consider a complaint that's more than 3 months old (i.e. more than 3 months has passed since the behaviour / action that you are complaining about).

Our commitment to you – we will:

- Take your concerns seriously and make every effort to help resolve them constructively, impartially and efficiently
- Acknowledge receipt of your complaint within two business days and provide a contact name in the BHBIA team for you to communicate with
- If we cannot resolve the issue straight away, keep you updated on progress
- Should the investigating team be extended to the Board and no resolution is found, the Board has the power to enact clause 15 – Expulsion of Member as outlined in the Articles of Association

To submit a complaint please fill in a contact form here: Contact | BHBIA or call us on 01727 896085.

This Complaints Policy can also be found online on the BHBIA website at:
https://www.bhbia.org.uk/about/legal_financial_and_policies/policies.aspx

References

[1] BHBIA Guidelines includes the BHBIA's *Legal and Ethical Guidelines for Healthcare Market Research*, ABPI/BHBIA *Guidance notes on collecting adverse events, product complaints and special reporting situations during market research.*

[2] BHBIA member companies include full members: corporate, affiliate and personal and certified non-members: corporate and personal. Companies that are sub-contracted to a BHBIA member company for a business intelligence project are also required to follow the guidelines, so would be covered by this policy, with the member company ultimately being responsible.

[3] Business Intelligence activities include, but are not limited to: primary market research, secondary data collection and analysis, syndicated data services, field force effectiveness services and fieldwork recruiting.

[4] The BHBIA guidelines only cover work conducted in the UK, however it does not matter where the member organisation or individual is based.

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

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

Anonymity Non-disclosure of identity.

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 an 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 secondary analysis (e.g. sentiment 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 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 organisations 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 HCPs or other relevant decision makers provide services.

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. The ABPI 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 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 HCPs.

Non-HCP could include a patient, sufferer, carer, family member, member of the public, journalist.

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.

Patient organisation means an organisation mainly comprised of patients and/or caregivers or any user organisation such as disability organisation, carer or relative organisation and consumer organisation that represents and/or supports the needs of patients and/or caregivers.

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Personal data: Personal data means any information relating to an identified or identifiable living person who can be identified directly or indirectly from that information, either alone or in combination with other information reasonably available to the controller or another person.

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, transfers 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 e.g. 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 an MR project.

Researcher Any individual, agency, organisation, department or division that offers their services, carries out, or acts as a consultant on an 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.

Responsible Adult is an individual who has personal accountability for the well-being of a child or a vulnerable adult, for example a parent, guardian, carer, teacher, nanny or grandparent. It is not an individual who has a limited or specific responsibility such as a lifeguard, instructor or employer.

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

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.

Special category data reveals racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation.

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.

L SOURCES

Our guidelines draw on the following sources.

* Denotes the source has been updated since the last Legal & Ethical Guidelines update.

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 2024*
- Market Research Society's Code of Conduct 2023
- ICC/ESOMAR International Code on Market, Opinion and Social Research and Data Analytics 2016

The following legislation is also vital in underpinning our guidelines:

- The Data Protection Act 2018
- EU General Data Protection Regulations 2016/679 (GDPR) as implemented into national law by the Data Protection Act (DPA) 2018.The Privacy and Electronic Communications (EC Directive) (Amendment) Regulations 2011

Other sources

- EphMRA – European Pharmaceutical MR Association
  - EphMRA Code of Conduct 2024*

- ESOMAR – The European Society for Opinion and Marketing Research
  - Briefing questions when considering tools and services for unstructured data – text, images, audio and video
  - ESOMAR/GRBN Online Research Guideline
  - Guideline for Conducting Mobile Market Research
  - Guideline for Researchers and Clients Involved in Primary Data Collection
  - Guideline of Research and Data Analysis with Children, Young People and Other Vulnerable Individuals
  - Guideline on Social Media Research July 2011

- 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, August 2022
  - MRS Guideline: Conducting data collection activities with children February 2020
  - Data Protection & Research: Guidance for MRS Members and Company Partners 2019
  - Guidelines on the Privacy and Electronic Communications Regulations May 2011
  - Best Practice Guidance on Mobile Adoption & Optimisation Best Practice Guidance February 2023
  - Guidance Note on Collecting Data on Sex and Gender June 2024
  - Guidance Note on Researching Age Bands for Over 65s, June 2016
  - Guidelines for Online Research September 2014
  - Guide to Observers' Legal & Ethical Responsibilities April 2024
  - MRS Guidance: ICO Age Appropriate Design Code April 2024
  - MRS Guideline: Qualitative Research April 2020
  - Questionnaire Design Guidelines April 2024
  - Use of Predictive Diallers June 2020
  - Using Research Techniques for Non-Research Purposes June 2020

M PRO FORMAS

Pro Forma 1 – Recruitment Script Template for use in conjunction with recruitment agreement (see Pro Forma 2) Part of an online screener (qual or quant) or read over the phone completed and sent back to the respondent

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 commissioning the MR>*** and would really value your opinion. [IF NECESSARY] We would prefer not to reveal the name of commissioning 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 this market research is to ***<purpose>*** and it will take the form of ***<interview type, duration, start time & location>.*** We will provide remuneration of ***<amount>*** paid by ***<method of payment>*** for your time and participation***.*** ***<Travel expenses will also be covered.>*** THIS INFORMATION MUST BE CLEAR AND SPECIFIC. Taking this opportunity to have your voice heard would greatly help us further our understanding 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
This market research will comply with Data Protection Act 2018/UK GDPR 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 e.g. 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 will only retain your personal data for as long as necessary to fulfil the purposes of this market research or as explained in our privacy notice. We will ensure that it is always kept secure and take necessary measures to process your data in accordance with UK Data Protection laws. For further details on how we protect your personal data, visit [privacy notice link]. For the purpose of reviewing for safety information, including adverse events and/or product complaints personal data will be retained by [AGENCY NAME] for a period of up to [X] years. If you agree to us sharing your personal data with the commissioning healthcare/ pharmaceutical company they will retain it permanently The ***<interview/group discussion>*** will be ***<observed live, 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 TO A THIRD COUNTRY: We may need to send some of your personal data to **<third country>** because **<reason>**. We will ensure 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 at that time whether you consent to us passing your details to the commissioning healthcare/ pharmaceutical 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.

Safety information follow-up activities will not be extended to any other data gathering activity.

Are you willing to continue on this basis?

YES Continue
NO Thank and Close

AE Reporting: Non-HCP – patient, caregiver or consumer

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 at that time whether you consent to us passing your details to the commissioning healthcare/ pharmaceutical 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.

Safety information follow-up activities will not be extended to any other data gathering activity.

Are you willing to continue on this basis?

YES Continue
NO Thank and Close

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Additional AI Statements to consider adding:

Please consider adding one of the following consent statements as required. These statements are intended to supplement, not replace, the existing information and consent requirements contained within the BHBIA Pro Formas. Researchers should ensure that any use of AI is accurately described and that respondents receive all information required under applicable data protection legislation:

Option 1 – To add where AI is used only on anonymised research data:
Use where AI tools assist with transcription, coding, summarisation, theme identification or reporting, but personal data is not intentionally processed by the AI system other than as necessary to create a transcript.

AI tools may be used to support the processing of your research participation. This may include converting the audio recording into text and analysing anonymised responses to identify themes, patterns, and insights. Your personal data will not be used in AI analysis except where needed to transcribe the interview. Once information that could directly identify you has been removed, anonymised versions of your responses may also be retained and used for future research analysis, including within secure research knowledge bases or AI-supported tools.

Are you willing to continue on this basis?

YES Continue
NO Thank and Close

Option 2 – To add where AI tools process personal data:
Use where personal data is actively processed by an AI application, including AI moderation, chatbot interviewing, sentiment analysis, automated coding of identifiable verbatims, AI-powered respondent engagement tools, voice analysis, or where data is submitted to third-party AI platforms before anonymisation.

AI tools will be used to process your personal data, for example [list use case here: real time chatbot interviewing, transcribing, data analysis and reporting, verbatim processing, sentimental analysis, AI training…]. We will use [List AI tools here, focusing on enterprise, closed or open AI, e.g. ChatGPT free/pro/enterprise; Claude free/max/enterprise; proprietary AI tools] for [list use case], details see [display privacy policy for each tool, e.g. https://openai.com/policies/row-privacy-policy/ ; https://privacy.claude.com/en/]. As a result, your personal data maybe retained by [AI tools] for [x years, or based on their terms].

Are you willing to continue on this basis?

YES Continue
NO Thank and Close

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 Market Research:	
Methodology and Approach	
Fieldwork	
Location: (If online or telephone, please state this)	Duration:
Date:	Start Time:
Remuneration	
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 BHBIA's guides:

- Lawful Bases for Processing Personal Data
- Consents for Market Research, What is required and when

Available at Guidelines & Legislation | BHBIA

Pro Forma 3 – Disclosure

Disclosure Notification

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 individual or organisation's identity is known to the commissioning pharmaceutical company and they will receive reimbursement (a payment for participation and/or expenses).

- Individuals must be told before fieldwork starts (generally at recruitment) how their personal data will be used for disclosure.
- A lawful basis for any disclosure related data processing must be in place.

The ABPI encourages the use of 'legitimate interests' however some companies may use 'consent' or may have contractual arrangements already in place with HCPs that include disclosure so no further agreement is required. However, whatever the lawful basis used, individuals must be told how their personal data will be used and they have the right to object to this.

General declaration – to precede the legitimate interests notification or the consent agreement

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. The information will include your name and address, as well as the value of the payment and any expenses paid to you, plus a description of the service e.g. market research. 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 commissioning healthcare/ pharmaceutical company website too]. The information disclosed has to remain in the public domain for at least 3 years from the time of first disclosure.

The purpose of disclosure is to enhance the transparency surrounding the relationships between the pharmaceutical industry and the healthcare profession.

Your market research responses remain confidential and anonymous even if your name and address (i.e. your personal data) is used for disclosure.

[OPTIONAL USE BY MR AGENCIES ONLY] We would prefer not to reveal the name of the commissioning 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 visit [LINK TO PRIVACY NOTICE] or contact [privacy e-mail]

Legitimate interests notification — **EITHER LI WILL APPLY OR CONSENT, NOT BOTH**

In summary, your name and address, the value of the payment and any expenses paid to you will be passed to the healthcare/ pharmaceutical company that commissioned the market research so that they can fulfil their disclosure reporting obligations. We will share your personal data under the commissioning company's 'legitimate interest' i.e. the commissioning company has a legally valid reason for this, it allows them to meet their ABPI disclosure obligations, and the commissioning company has carefully balanced your individual rights against this need. For more information on legitimate interests please visit [LINK TO PRIVACY NOTICE] or contact [privacy e-mail]. [DPO officer details inserted here]

You have the right to object to this but if you do, unfortunately it may not be possible to include you in the market research. [END CLIENT MUST ADVISE ON NEXT STEPS IF THE INDIVIDUAL OBJECTS]

Consent agreement — **EITHER CONSENT OR LI WILL APPLY, NOT BOTH**

In line with the ABPI Code of Practice for the UK Pharmaceutical Industry, the UK Data Protection Act 2018 and the UK GDPR,
[By signing below/clicking on the box/returning this email] (AMEND AS APPROPRIATE)

- 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 e.g. place of work, address:	

Pro Forma 4 – Receipt of Reimbursement

Receipt of Reimbursement (QUAL)	
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: • The exercise in which I am taking part is sales aid market research 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 • Any stimulus materials shown are for exploratory purposes only and are not intended to be promotional	
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	
I understand that the commissioning healthcare/ pharmaceutical company of this market research _____ (name of recipient organisation(s) may or may not be required) will: DELETE AS APPROPRIATE – ☐Watch through a one-way mirror (watching organisations do not need to be named) but type of organisation(s) should be specified) – ☐Listen to the interview live as it happens – ☐Watch the interview live as it happens – ☐Listen to an audio recording at their offices (organisations listening in may or may not need to be named depending on whether audio information is considered personal data or not) – ☐Watch a video recording at their offices (watching organisation(s) must be named but naming may be delayed until the end of the interview if viewing is not live) I understand that the purpose(s) of the commissioning healthcare/ pharmaceutical company having access is: _____ _____ _____ The people in the commissioning healthcare/ pharmaceutical company who will listen to or view the recordings will be in the following functions/roles: _____ _____ _____ I understand that all those observing live/ listening or viewing a recording must respect the confidentiality of all information exchanged in market research interviews/groups and that no sales approaches will ever be made to me as a consequence of the company having this access. I understand that I can withdraw my consent at any stage. IF APPROPRIATE We would prefer not to reveal the name of the commissioning 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	
Signature	
I have read, understand and agree to the terms detailed above.	
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 Guidelines & Legislation | BHBIA and for more information on naming the end client see: Data Protection – Naming the End Client Data Protection Update – Naming the End Client | BHBIA

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	
On behalf of **<** commissioning healthcare/ pharmaceutical company **>** I can confirm that the recording(s) of MR fieldwork from the above market research will only be used for the following purpose(s): _____ _____ _____ The only people in the commissioning healthcare/ pharmaceutical company who will listen to or view the recordings will be in the following functions/roles: _____ _____ _____ And the recording(s) will be in the secure care of: _____ On behalf of the commissioning healthcare/ pharmaceutical company can confirm that: • 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. • If video streaming has been used to allow remote viewing it is possible that the video transmission system used delivered a copy of the recording to the receiving computer. If this is the case any copy of the video stream saved on the observer's computer MUST be deleted.	
Signature	
I have read, understand and agree to the terms detailed above.	
Company Signature:	Name (please print):

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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	
Observers must be familiar with and adhere to the BHBIA's Legal and Ethical Observers' Guidelines. Observers must be introduced openly and honestly to respondents. 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 observer must also withdraw from observing. However, if respondents are made fully aware of the presence of an observer known to them and give explicit consent for that individual to observe then that person may remain at the session - care should be taken that the respondents are completely comfortable if 'put on the spot' in this way. Observers must respect the confidentiality of all information exchanged in MR interviews/groups. They must not at any time: • 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):

N PRACTICAL EXAMPLES

Questions listed by section, then in order of appearance

E1.3 Proof of competency

As a MR agency we sometimes request quotations from potential suppliers with whom we have no pre-existing contract in place. We are concerned that confidential information might be shared with a potential supplier before any confidentiality agreement is drawn up, what should we do?
- If it's not practical to forward a confidentiality agreement prior to seeking the quotation, it is advisable to risk assess and seek proof of competency from them before sharing any confidential information.
- If this is not practical, you should make sure that all sensitive or confidential references are disguised or removed, to protect the information.

E2.1 Proposal content

Fieldwork agencies should inform their clients at proposal stage if sub-contractors are to be used but this isn't always known at this stage, how should we handle this?
- Principle 12 underpinning the BHBIA's Legal & Ethical Guidelines says "We must conduct our MR accurately, transparently and objectively". In addition, if the sub-contractor is a data processor or sub-processor there is a data protection requirement to make them known to the data controller.
- The requirement to be transparent clearly suggests that the use of sub-contractors should be acknowledged as and when they are brought into a study even if their use was not anticipated at the planning stage.
- In addition, the ABPI Code requires that that members are accountable for their third party suppliers.

E3.2 Sample size

Can I conduct MR in a Rare Disease area where there are very few specialists and patients to sample?
- Caution needs to be applied in cases where the sample is so small that by interviewing a few respondents you may be covering a disproportionate percentage of the universe. In such cases MR could in fact be perceived as disguised promotion, depending on the subject matter covered and it may prove harder to anonymise personal data
- Consideration could be given on whether the insights required can be gathered through other means such as literature reviews, social listening, and advisory boards

E4.1 Key recruitment principles

We are using two different providers to recruit respondents for a study – is it necessary to share the script/wording that will be used with respondents by these different providers with the end client?
- The recruitment screener is usually reviewed/approved by medical and compliance personnel in the end client company, in line with the ABPI Code of Practice which requires all MR materials to be examined to ensure they do not contravene the Code or any legal requirements. Clients may also have internal company specific guidance they need to adhere to e.g. fair market value rates
- Should the recruitment providers wish to make any changes to the agreed wording, including honoraria, this would need to be shared with and approved by the end client as they are ultimately liable to answer any complaints raised by the PMCPA in connection with the MR, and in such circumstances it would be expected that the end client has oversight of all the MR instructions/materials associated with the project

Can we use MR outputs for a non-research purpose e.g. database building or rep training?
- Separate, independent consents for participation in the MR and the non-MR must be secured at recruitment.
- So if for example, awareness and usage data is collected from a sample of specialists and the findings presented in anonymised, aggregated format for MR purposes, this constitutes one purpose. If in addition, a list of the respondents was provided to the end client for marketing purposes, this is a separate non-MR purpose and must be clearly distinguished from the MR use.
- The same would apply if a request was made to use non-anonymised film footage of patients discussing their conditions during the course of a MR interview for training purposes.
- Anonymised aggregated MR findings may be used in different contexts e.g. in a press release or a detail aid, as long as it's clear they are MR findings and the requirements for publishing them have been met – see section E7.3

E4.2 The recruitment agreement and securing consent

If a business consultancy commissions MR from an agency on behalf of a pharmaceutical company, who is the 'client'?
- In terms of the BHBIA's guidelines, the client is the commissioning party and the agency is a sub-contractor executing the study on their behalf.
- The client is generally but not always a pharma' company.
- When a 'middle man' e.g. a business consultancy acts on behalf of a pharma' company, the consultancy is generally still a sub-contractor (unless the work is being carried out completely independently of the pharma' company) so it could be said that the consultancy is the active client and the pharma' company the ultimate client.

The end client, a pharma' company, has been informed by their legal department that revealing their name, as commissioning the MR, would breach the ABPI Code of Practice (even if they are a data controller, a source or recipient of personal data
- The ABPI Code of Practice, clause 5.6 states that 'market research material if it is such that the name of the company involved is not required to be stated, then the material must state that it is commissioned by a pharmaceutical company"
- If the end client is a data controller, a source or recipient of personal data, their name needs to be revealed in order to comply with data protection requirements.

We are joint data controllers for data processing taking place for the purposes of MR, can we name just one data controller rather than both?
- Joint data controllers must both be named.

Do we have to tell interviewees the end client's identity if they don't ask for it?
- Organisations have a responsibility to provide information that data subjects are entitled to, which may include the identity of the end client.
- It is not the individual's responsibility to ask for this information.
- The requirement to be transparent demands that data subjects are provided with the information they are entitled to as soon as practical and there has to be a clear justification for providing this information at the end of an interview.

How should consent be recorded?
- For written consent, a copy of the consent statement or data capture form.
- If online consent was given, your records should include the data submitted and a timestamp to link it to the data capture form.
- For oral consent, keep a record of the fact that consent was given and make this record at the time of the conversation.

E4.3 Disclosure requirements

Is disclosure required if a donation is made to a charity instead of remuneration?
- Yes (assuming the identity of the HCP/HCO is made known to the end client), disclosure is required whether or not the MR payment was made directly to the HCP or to a third party e.g. a charity.

If we use a client supplied list do we have to disclose?
- Not unless the client company was intentionally made aware of the identity of the individuals sampled from the list that participated in the MR activity and a transfer of value (honoraria/remuneration , expenses, etc.) was made to the participants.
- If however the goal is to interview all HCPs on the list (i.e. complete a census), then their identity will be known and disclosure will be required.

E4.4. Recruiting from a list or database

We want to recruit sufferers via an advert on Facebook which would show up on their landing page if they have expressed an interest in discussing their condition, we only want to capture the IP address; can we do this?
- There are no MR guidelines that prohibit online recruiting via an advertisement on a social media site.
- However the content and tone should be designed such that it cannot be misconstrued as disguised promotion.
- The online service provider's (i.e. in this case Facebook's) terms and conditions should be reviewed to make sure that this approach does not breach them.
- The UK GDPR states that IP addresses should be considered personal data so must be treated as such and you must have a lawful basis for collecting this.

We want to approach potential respondents for a B2B MR project via LinkedIn, can we do this?
- There are two key issues to consider:
1. Do the terms and conditions of the website allow this? Some may prohibit it.
2. You must have a lawful basis for the use of the personal data for your purpose.
- You should also bear in mind that you are obliged to inform potential respondents that you are working on behalf of a competitor company (if this is the case) as you have an obligation to process personal data not just legally but fairly and transparently too; and with due regard for any consequences for the data subject.

If a list is provided by the end client for matching with a fieldwork agency's panel to produce a single list for recruitment, who is the 'source' of the personal data for data protection purposes?
- The end client is likely to be the data controller for their in-house database (from which the list of names they supplied was drawn)
- The fieldwork agency is the data controller for their panel
- But the two organisations are likely to be joint 'sources' for the matched list in data protection terms.
- The list resulting from the match is a result of two lists – the original and the panel – and so there are two sources for the matched list - after all it couldn't exist without either one of the two original sources)
- Whilst both sources have to be identified as the source of the list/personal data, only the fieldwork agency will be in direct contact with the data subjects and so they should be responsible for facilitating data subjects' rights and this should be made clear.
- This is the case irrespective of whether or not the end client has access to any personal data of those that were recruited fed back as part of the MR.

If a pharma company licences or buys a list of physician details from a CRM provider and this list is used to recruit individuals in to a MR survey commissioned by the pharma company, who should be named as the source of the personal data?
- The pharma company must be named as the source even when the names were supplied by a CRM provider – as the pharma company initiated the supply.
- Data protection law requires that when personal data is not obtained directly from the individual, the individual must be informed of the source of their personal data.
- The CRM provider should also be named as well to be as transparent as possible.
- An additional agreement may also need to be signed between the list supplier and the fieldwork agency detailing the ways in which the list data can or cannot be used.

Can we link respondent-specific data over waves of a tracking study?
- Yes, as long as it is made clear to individuals participating in longitudinal MR in advance of wave one that over time their input could or will be linked and they understand and give consent for this.
- Principles 1 and 7 of the BHBIA's Legal and Ethical Guidelines require researchers to be transparent with regard to their use of data. The BHBIA Guidelines define 'transparency' as ensuring individuals have a very clear and unambiguous understanding of why the data is being collected and how it will be used.
- Providing information and seeking consent retrospectively does not qualify as informed consent, individuals must be informed 'up front' how their data will be used.

Can we flag individuals as 'do not contact for MR'?
- In order to make sure that people that don't want to be contacted for MR aren't, we have to flag this on their record.
- You do not need the individual's consent for this.
- This is not the same as an individual asking to have their details erased.
- This flagging must not be used for any other purpose e.g. contacting them to ask why they don't want to do MR.
- You can supply the flagged data to the list supplier but the supplier should confirm in writing they understand and agree the data can only be used for 'do not contact' purposes.

E4.5 Handling data

What are the compliance implications of asking doctors to name Key Opinion Leaders (KOL) in a MR survey?
- It depends upon the purpose of the work (i.e. why the names are being collected), if it is:
a. Purely for MR e.g. the names are being used for KOL mapping and no direct action will be taken with regard to those named, then there are no data protection requirements with regard to the KOLs named when their names are collected.
b. To develop a sample of KOLs for MR, then the BHBIA's guidance on snowballing applies, (see section E4.5). Remember you must have a lawful basis to store an individual's personal data, in this case it is likely to be legitimate interests and all other data protection requirements with regard to the collection and storage of personal data must be met.
c. Database building for future use (e.g. for promotion) – this is not a MR activity and must not be represented as MR; it is also outside the scope of the BHBIA's guidance.

E4.6 Re-contacting respondents

On completion of a MR project, we've come up with some new ideas we'd like to test based on answers that were given to us in the MR. Can we go back to the original respondents to see what they think?
- Not unless this was specifically mentioned to the respondents as part of the original project. If it wasn't, then testing the ideas would have to be part of a new MR project.

Can we contact respondents of a previous wave of MR to ask them if they want to participate in the next wave?
- If you have asked them specifically if they may be re-contacted for this purpose, you may go back to them directly.
- Otherwise, they must only be contacted via the usual recruitment methods used with new respondents e.g. through panel invitations etc.

The agency has identified instances of off-label usage in the data at the analysis stage and want to share the personal data of HCPs with the end client's pharmacovigilance team, but the HCPs were not made aware of the commissioning company's identity because they determined they were not a data controller for the MR or the source or recipient of any personal data as a direct result of the MR, so can we do this?
- If the commissioning company determined they did not meet the criteria for these 3 scenarios and were not revealed at any stage in the study, you cannot transfer any personal data to the commissioning company's pharmacovigilance team.
- AE reports will need to be submitted anonymously.
- If you have the appropriate consent for re-contact in place, you may be able to ask the HCPs for the permission to share their details if the commissioning company is named first, but this is unlikely to be the case if this requirement was an afterthought. Proceed with caution if looking to capture consent for a separate purpose after the fact.

E4.8 Recruiting patients through doctors

How much information do I need to give the doctors being asked to recruit patients?
- Doctors who are recruiting patients for MR should be made aware of the details of the study as per normal informed consent.
- They should be aware of what will be expected of the patients they approach in order to make a decision as to which patients are suitable.

The doctors we have spoken to are asking us to confirm which patients they spoke to took part in the study. They think it will be awkward to meet them again and avoid the subject. Is this OK?
- If patients choose to volunteer this information to the doctor who nominated them for the MR at their next meeting, that is their prerogative and does not need to be actively discouraged
- However, you should not share that information with the doctors directly.
- Doctors should be discouraged from asking nominated patients if they participated in the MR, this could be considered as putting unfair pressure on patients

When using HCPs to refer patients for participation in a MR project, do we have to declare a fee given for this in our recruitment costs?
- Yes, any fees associated with recruitment must be made clear.
- All forms and levels of reimbursement (including expenses) must be made clear as soon as practical, ideally at proposal stage and should be within the FMV rates of the commissioning client, if applicable.

E4.9 Reimbursing respondents

A fieldwork agency has asked to pay respondents in either cash or vouchers, is this allowed?
- Yes, providing signed receipts are received and the amount is not above the agreed remuneration amount and FMV. Some companies have internal guidelines on payment methods to HCPs, this should be made clear in the proposal and the form of payment must be clear at recruitment.

An agency has suggested that a group discussion is held at an expensive hotel as it is a convenient location and that a dinner should be provided after the discussion for the HCPs, is this allowed?
- In accordance with Clause 10 of the ABPI Code of Practice, arrangements for meetings must comply with Clause 10.1 with regard to hospitality and venues.
- The venue must be appropriate and conducive to the main purpose of the event/meeting; lavish, extravagant or deluxe venues must not be used
- any associated subsistence (food and drink) must be strictly limited to the main purpose of the event/meeting, must be of secondary consideration and must be appropriate and not out of proportion to the occasion
- It would be necessary to take into account the cost of the dinner and whether this would take the total reward/remuneration for taking part above the FMV, if so, it may be considered as a promotional activity.

Does providing remuneration for MR contravene the Bribery Act 2010?
- Bona fide market research does not contravene the Bribery Act 2010.
- The Act is concerned with bribery. Very generally, this is defined as giving someone a financial or other advantage to encourage that person to perform their functions or activities improperly or to reward that person for having already done so.
- MR work that meets the BHBIA's definition of MR and is run in accordance with the BHBIA's Legal & Ethical Guidelines (including those on remuneration) does not encourage respondents to "perform their functions or activities improperly or to reward that person for having already done so".

A MR agency is working on a qualitative project for a new entrant into a rare disease area which has a very limited number of HCPs who are all senior consultants. The fieldwork agency have recommended a higher remuneration than the standard FMV given by the end client, can this be justified?
- It may be justifiable on the basis of the small universe and status of the target audience but it must be discussed and agreed with the end client.
- The setting of remuneration should be a transparent process with all parties in the MR chain aware of the levels and implications of any limits imposed.

Can we collect respondents' bank details to make payments via BACS transfer?
- This is permitted.
- Keep the personal details of reimbursed respondents secure and confidential.
- Make sure the respondents' personal data is not accessible to anyone outside the agency and don't pass these personal details to the client.
- If you're an end client doing your own MR, these personal details must not be accessible to anyone outside the research team or company personnel involved in processing the reimbursement.
- For details of the guidance when handling and storing personal data see sections E4.5 and E7.1.

E5.1 Question and questionnaire design

If we carry out a patient case record study are there any data types we are not allowed to collect?
- There are no specific data types that cannot be collected for MR purposes
- HOWEVER if personal data is collected the patient's explicit consent is required as this is special category personal data.
- If only anonymised data is collected patient consent is not required but care must be taken to make sure that a combination of different data items could not be used to identify the individual e.g. age, sex, condition and location, so we advise that you collect general information rather than specific items wherever possible e.g. age band not age in years, city or county not postal district
- It is essential that researchers take reasonable steps to make sure that the data collected is relevant and not excessive.

We want to include a question in the screener to better understand the kind of audience being targeted (even if they are not recruited), can we do this?
- No, the screener should only be used to establish whether potential respondents are suitable to take part in the MR or allocate them to a quota.

E5.2 Disguised promotion

We want to ask patients to search online for information about a specific type of drug as part of a MR project, would this be considered disguised promotion?
- Not necessarily, it will depend upon the way in which the request is framed and many other aspects of the project.
- It is essential that the request/instruction/question directing the respondent to look for material should be general and balanced, it should not lead the respondent to the commissioning company's product more than a competitor's product.
- The work must not encourage the patients to ask their doctor to prescribe a product or offer advice on the specific therapy area being discussed.
- Bear in mind that giving the impression that the MR is disguised promotion may result from the cumulative impact of several factors – see section H4 for more information.

Can we show respondents a list of brand names and ask them if they use any of these drugs?
- Yes, you can use a list of drug brand names as stimulus but it does have to be handled with care in order to avoid being misinterpreted as disguised promotion.
- Their use must be essential to meeting justifiable MR objectives.
- It is advisable to include a series of competitor brand names to obscure the focus of the MR.

E5.3 Sensitive topics

How do I know if a topic is sensitive?
- Put yourself in the place of the respondent, their experiences, condition, lifestyle etc. If you were them what would you think?
- Exactly what is it that you are seeking in the research? Could it generate an emotional response from the respondent?
- Discuss it with your internal team – everyone has different perceptions and sensitivities which may prove insightful.
- Patients and Carers may be struggling with the subject under discussion – even during the interview look for signs of unease and moderate the questions accordingly.

If in doubt – treat as sensitive

E5.4 Stimulus material

Can we test concepts in MR that could not be used in promotional material?
- Yes, the content that may be included in MR stimulus material (e.g. product concepts) is not bound by the same regulations as the content of promotional material that is to be published. The ABPI Code of Practice makes it clear that promotional materials must meet tightly defined requirements (Clause 6 Information, claims comparisons and disparagement).

What type of content is permissible in a target product profile for a product not yet launched in the UK?
- Must remain unbranded
- Must be introduced as hypothetical in nature

- Data included, and especially that which is clinical in nature should be within the bounds of sensibility for the product
- Should not include any hidden pointers to lead the respondent to identify the product
- Beware of any potentially promotional phrases included – these could be considered disguised promotion.

Do you have to show the black triangle alongside new products in MR materials?
- No, not necessarily, MR materials are not promotional materials. The ABPI Code (clause 12.7) requires black triangles (when required by the licensing authorities) on all promotional material and on summaries of product characteristics and on package leaflets.

We want to send a new version of our product packaging to HCPs recruited by a fieldwork agency so they can provide feedback on it in a later IDI, is this okay?
- Whilst there are no laws, regulations or guidelines that prohibit this, it must be approached cautiously because:
- You have no control over what occurs to the packaging – even if it is labelled as being in development, it could be mishandled
- It could be considered disguised promotion if branded
- Our recommendation would be to make sure you retain control over the packaging at all times during the MR process and use a methodology that allows you to do so

E5.5 Testing products and devices

Can we test live or active devices?
- Yes but in addition to the guidance remember this option should be a last resort and avoided if possible
- Consider the transportation implications
- Respondents must be carefully trained and supervised when handling the device, with handling kept to a minimum during the research – safe handling is paramount.
- If respondents include patients, the patients selected must fit the criteria for those who would be prescribed the product or who are already using a similar device
- Devices must not be left with the respondent and must be collected and returned to the client at the end of the research.

What do we do if training participants to handle potentially harmful devices (e.g. those with a needle) would undermine the need to assess handling amongst those new to the device?
- If the purpose of the usability testing MR is to test the usability of potentially harmful devices amongst naïve users, i.e. those using the device for the first time and assess their reactions, then it would not be appropriate to train them prior to use. Once trained, they know how to use the device and so you would not be able to gather data on the errors that they might make without training and which device developers could mitigate. So prior training on device handling may not always be appropriate. However, participants must be given all the information and support they would normally receive in the real-world situation and fieldwork must always be supervised so that intervention can take place if necessary. In addition, all device MR work should be carefully risk assessed before it takes place; device handling must be as safe as it can be. We also recommend that the end client's medical department is involved.

E6.1 Conducting fieldwork – Information to be communicated

Can an end client company employee participate in a MR interview?
- Yes, this is permissible, a company market researcher could carry out the interview or a member of the brand team could present stimulus material.
However:
- Their company's name must be made clear to the interviewee before the interview.
- Their role must be non-promotional.
- They must not be familiar with or known to the respondents.
- They must respect the confidentiality of all information exchanged during the MR.
- A written agreement detailing the terms above should be provided and signed.

E6.3 Observing, listening in and recording

A respondent wants a copy of the audio recording of a recent interview, it contains confidential competitive intelligence; do we have to provide it?
- This depends on whether the audio recording is considered personal data or not.
- If it's not personal data and you have not entered into any contractual arrangement to provide copies of interview recordings to respondents then you are under no legal obligation to do so. The decision should be made in conjunction with the end client.
- However if the audio recording is considered personal data then depending upon the lawful basis for collection of the personal data the individual may have the right to access to the recording.
- If consent was the legal basis for the data processing then the data subject has the right to access and you have one month to respond to an access request.
- If confidential competitive intelligence is made available it should be protected by a non-disclosure agreement (NDA).

Is it possible for US based end client employees to listen in to UK based MR interviews?
- Yes, as long as respondents have given their informed consent for this.
- Irrespective of whether the respondents are identifiable or not to the end client respondents must be told the interview will be listened to by representatives of the end client/a pharma' company and give their consent to this.
- However there may also be specific privacy/data protection requirements too. Key to understanding whether data protection requirements apply is knowing whether the voice alone is personal data or not (assuming no other personal data is communicated during the interview e.g. names).
- If the voice is not personal data protection requirements do not apply.
- If the voice is personal data, then:
- The end client is receiving personal data and must be named as a recipient before any listening-in takes place.
- There must be measures in place to guarantee the lawful and secure transfer of the personal data to the US based company personal listening-in e.g. UK standard contractual clauses or binding corporate rules.

E6.4 Observer behaviour

We may need to keep recordings for AE/PC/SRS reporting purposes for longer than MR purposes; can we do that?
- You can store non-anonymised recordings for as long as you have a valid lawful basis for processing the personal data for AE/PC/SRS reporting purposes. If your legal basis is consent, make sure the consent is recorded.
- An anonymized full copy of the recordings' content, (such as a validated transcription of the interview) is considered to be a validated copy of the original source data and so can be kept instead of the original recordings.

E7.1 Storing and accessing respondent data

How do we validate/check survey answers if personal data are removed?
- If validation is required, a pseudonymised ID can replace the personal data.
- Personal data should be maintained by the fieldwork agency in a secure and separate location to ensure data security.
- If validation is required, a request should be made to the fieldwork agency to the authorised personnel who have access to personal data (as this should be limited), it should not be possible for just anybody within the company to access this data.

E7.2 Reporting

Can we include images/videos extracted from the public domain?
- Copyright of images/videos/posts from the public domain belong to the party posting them, not the research agency.
- Their inclusion should observe the Terms of Use from their original site
- Reference to the author or sites should be made and copyright origin stated

E7.3 Publishing

Can we use MR findings in a publication or at a conference?
- Using aggregated and/or anonymised MR findings as MR outside the company is allowable.
- This does not require separate consent.
- PMCPA (ABPI) advice is that the output shared must be considered "appropriate" information and that safeguards e.g. such as terms and conditions for its use, should be agreed in writing.
- So publishing MR findings as MR data in a journal or at a conference is allowable as long as BHBIA guidelines are followed.
- Make sure quotes cannot be traced back to the respondents, either through the content of the quote or through the generic profile you will use to contextualise it
- MR outputs cannot be used for a completely different purpose unless they are kept in context, it must be clear that you are quoting MR findings and these are quoted accurately and subject to the BHBIA Guidelines on Reporting and Publishing

E8.2 Closing off – Data storage

How long can MR records be stored for?
- MR records must be destroyed when the purpose of the study is redundant.
- There are no absolute guidelines on how long this should be.
- Storage length will vary according to the nature of the data, the type of project and the need for further MR or follow up analysis.
- Personal data (e.g. recruitment questionnaires or remuneration receipts) may well be destroyed before non-personal data (e.g. data tables).
- The period of storage should be agreed with the client in advance.

F2 Vulnerable respondents

We are carrying out MR with patients that may express suicidal intent, how should we handle this?
- Researchers have a duty of care to respondents when MR is undertaken, it is built into the basic principles of the BHBIA Guidelines.
- Whilst we can provide general guidance on working with vulnerable respondents (section F2) the BHBIA cannot provide detailed guidance for the most appropriate actions for all vulnerable respondent types.
- The responsibility for detailed guidance lies with the commissioning client company, as the end client and experts in the therapeutic area, their medical and marketing departments should advise on what support would be most appropriate e.g. Samaritans, mental health resources and patient groups/associations.

G1 Face to face interviewing

What is an acceptable form of identity card?
- Company issued ID, driving license, or other photo IDs

G2 Telephone and mobile phone interviewing

The client has developed an app and would like to have it tested via MR. The app collects personal data including special category data. The end client is a data controller but would like to run this as double-blinded and therefore not to be named prior to participants using the app. Is this possible?
- In accordance with the GDPR/UK Data Protection Act 2018, The end client is a data controller – data controllers relying on consent as their lawful basis for data processing must be named at the time the personal data is obtained from data subjects
- 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 in accordance with the conditions set out in the Guidelines.

G3 Observational (ethnographic) MR

We will be recording behavior (for observation) within the waiting room of a clinic, but we won't include any personal data captured in the deliverables. Do we need to obtain consent from each clinic attendees?
- Yes, irrespective of whether personal data is included in the deliverables or not, informed consent for recording and observation for a) doing this for the MR must be secured as well as b) recording any personal data (if this is to happen) even if the footage is anonymised before being shown to the end client

The data we recorded are really impactful and the client would like to present them (non-anonymised) at public conferences as part of an educational film, can this be done?

- You must obtain participants' separate informed consent to pass their personal data to the client for each purpose for which the data will be used.
- Participants' consent must be recorded for each purpose e.g. MR use and educational use
In case of special category personal data, the consent must be explicit

G4 Online/internet MR

Is digital consent allowed?
- Yes, as long as it can be recorded, it cannot take the form of a pre-ticked box.

G7 Testing sales aids

We have been asked to research some new and existing detail aids online, is this allowed and could it be construed as being promotion?
- Detail aid pre and post testing is both legitimate and reasonable.
- There are no guidelines which directly or indirectly suggest that it cannot or should not be done online.
- Whether a study is vulnerable to the accusation of disguised promotion depends upon a variety of factors, these are listed within the definition of disguised promotion within section H4.
- Remind respondents to respect the confidentiality and not to record, make notes nor attempt to take screenshots of all information shown during the interview

IF the interview had been carried out face to face or by telephone:

- Care should be taken to be consistent with all respondents around the information shared.
- Interviewers should not enter into unrelated conversations with respondents or answering more complex questions whose answers are not found in the materials. Questions or points of clarification should be noted down to be passed on to the moderator as aspects a respondent would ask or discuss in a real- life setting.

How can you guarantee that materials being tested will be kept confidential when conducting interviews online or by telephone?
- Respondents should be told that all information being shared in the MR is to be kept confidential – this should be part of the recruitment agreement they sign, and they should be reminded again of their confidentiality obligations prior to the start of fieldwork
- The materials being tested should include copy stating they are for MR purposes only and confidential
- Avoid sending any materials via email or in hard copy prior to the interview, and instead use a screen sharing platform to show materials during the interview

G8 Follow-up studies of representatives' visits

What steps must be followed if a respondent from a call list supplied by the end client company requests a correction to their details and/or not to be contacted any more in the future?
- This information must be passed to the commissioning company that had supplied the list - please refer to section 4.4 of these Guidelines - Correcting Contact Data and Erasing Data

H3 Research Ethics Committee approval

What are the distinctions that can be drawn between healthcare MR and health research?
Health research is a very broad 'school' and includes biomedical research including clinical trials and non-interventional studies, epidemiological studies, health services research, public health research, studies of behavioural, social, and economic factors that affect health, evaluation of health care interventions and services and drug safety surveillance.
MR (as defined by the BHBIA) attempts to generate understanding and knowledge of a market place and its consumers' behaviour through the collection, use, or analysis of information, this is very similar to the definitions used by the MRS, ESOMAR and EphMRA.
Confusion between MR and health research can arise because they sometimes address the same audience, may use a similar tool – a questionnaire or discussion guide, and can ask similar questions. In particular, non-interventional studies (or post-marketing authorisation studies as they may also be called) are confused with MR.

However, key distinctions between MR and health research include:

<u>Healthcare MR VS Health research</u>

<u>Purpose</u>
Healthcare MR = Commercial focus/purpose (market behaviour and opportunities) – designed to inform business decision making
Health research = Clinical or medical focus/purpose (safety, efficacy, pharmacokinetics, quality of life) – designed to advance science, the treatment of disease and improve patient outcomes

<u>Endpoints</u>
Healthcare MR = Clinical endpoints not required, no requirement to generate scientifically sound evidence
Health research = Clinical endpoints required, goal is to generate scientifically sound evidence

<u>Protocol</u>
Healthcare MR = Written protocol not essential
Health research = Written protocol as required

<u>Method</u>
Healthcare MR = Epidemiological methods not required
Health research = Epidemiological methods must be used to design the study and analyse the data

<u>Remuneration</u>
Healthcare MR = Participants are generally financially incentivised
Health research = Participants are not generally incentivised

Management
Healthcare MR = Managed by commissioning company's commercial teams generally marketing
Health research = Managed by commissioning company's scientific/medical service or individual's medical/academic supervisor

Approval
Healthcare MR = Does not require REC approval
Health research = Normally requires REC approval

Publication
Healthcare MR = Unlikely
Health research = Likely

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