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ETHICS & COMPLIANCE

Data Protection Requirements

Consents for Market Research
What is required and when

Introduction

This guide provides detail upon the different consents that might be required during the course of a primary market research project and at what stage these consents must be secured, before or during fieldwork.

The guidance takes account of UK and EU General Data Protection Regulations (GDPR) and UK Data Protection Act 2018 requirements. It complements the BHBIA's guide *'Legal Grounds for Data Processing'* available on the BHBIA website.

The BHBIA's Ethics & Compliance Committee is providing this guidance as general information for its members. It is not legal advice and should not be relied upon as such. Specific legal advice should be taken in relation to any specific legal problems or matters. Whilst every reasonable effort is made to make sure the information is accurate, no responsibility for its accuracy or for any consequences of relying on it is assumed by the BHBIA.

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Consent

The following bullet points summarise BHBIA's guidance on Consent and are drawn from *Legal Grounds for Data Processing (available on the BHBIA website).* Consent must be given by a clear affirmative action

- Consent must be freely given, clear, obvious and informed
- To secure consent to process personal data for MR, potential respondents must be told
    - Who is collecting the data and who is going to share it
    - Why - for what purpose
    - Any other information required to make an informed decision
- Consent is always specific to a single purpose
    - Personal data can only be used for the purposes for which it was collected
    - If you pass on personal data to colleagues inform them of the purpose(s) for which it can be used
- Explicit consent is necessary for processing special category (sensitive) personal data such as health data, automated decision making or overseas transfers to countries without adequate safeguards. Explicit consent must be confirmed in a clear and specifically worded statement.
- Consent or refusal must be recorded
- Individuals can withdraw their consent any time they want to and It must be as easy to withdraw consent as it was to give it.

General recommendations

- If you need to record a participant's consent for more than one purpose, combine these into a single form, especially when a participant is taking part in multiple stages of a project e.g. an online survey followed up by a telephone interview. The unified consent form can include, for example, the following distinct sections for consent purposes
    - consent to take part,
    - consent to the follow-up
    - consent relating to AE/PC/SRS reporting
    - consent to use the deliverables for publication
    - consent to use the deliverables for training purposes, etc.

  However, be careful to capture individual agreement to each action (e.g. using an empty tick box alongside each consent statement for participants to freely express their choices), do not bundle different activities into one over-arching consent.
- Consider creating a "consent pack" for participants including, at least the research leaflet, the privacy notice and the consent form, so that participants have to hand all of the information that is required to secure fully informed consent.
- Ensure fieldwork agencies or recruiters have all the necessary information and materials at the start of recruitment, so that appropriate consent(s) can be recorded as early as possible in the recruitment process and relevant information shared with participants upfront

- Electronic methods to record consent will make it easier to provide a hyperlink to an appropriate Privacy Notice, or 'hover over' functionalities to provide more information. They also make it easier to securely store consent records in a central location or platform.
- Consent records retention – be aware consent forms may include personal data or pseudonymised data and should be stored in secured location in line with the data protection agreement.

Signatures

Industry regulators both market research and pharmaceutical (i.e., the ABPI, the MRS, EphMRA and the BHBIA) as well as the UK's data protection regulator, the Information Commissioner's Office (ICO) do not require signatures ('wet' or otherwise) for consent agreements. Consent can be captured by a variety of means, signatures are acceptable but so too are e.g., answering yes to an oral request, ticking or clicking on an opt-in box online, selecting from (equally prominent) yes or no options, and there are other means.

Whilst it is important to highlight that a signature, wet' or otherwise, is not required for consent agreements, we recognise that some commissioning/end client companies require signed forms. You may need to investigate or seek advice in relation to the legal status of certain solutions and the features they provide, for example, electronic signatures.

- **If a signature is required:**
  - If a signature is required, use DocuSign, Adobe Sign, or another e-signature service. It is faster, more user-friendly for participants and better for centralised record-keeping.
  - Be thoughtful about your participants (e.g., patients, including vulnerable audiences) and leverage the accessibility of digital platforms, including screen reader options, mobile-friendly forms etc. to make the process as straightforward as possible for all participants.
- **If a signature is <u>not</u> required:**
  - Set out your consent agreement in an online form or survey link with an appropriate tick box to record consent. This approach has the added benefit of reducing the footprint of the personal data you process, as the consent can be pseudonymised and stored without further processing i.e. it does not require the participant to enter their name or to send a scan or picture of their form via a potentially less secure channel like email. It is important that the technology records the consent including a date and time stamp and information to identify which participant consent is being recorded for.
  - Record verbal consent, even if a signature is not necessary (or practical) e.g. when conducting telephone quantitative interviews, verbal consent must be recorded, such as by date/time record.

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Naming Data Controllers

- 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.**
    - Remember the end client is a data controller if data processing carried out by a joint controller or processor (e.g. an agency) is taking place for the end client's overall purpose. This is the case even if the end client never accesses any personal data.
- 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

This guidance is consistent with Market Research Society's (MRS) guidance on this issue available within section 3.4.2 of the MRS Guidance on Data Protection & Research 2019 available on the MRS website

https://www.mrs.org.uk/pdf/MRS%20Data%20Protection%20and%20Research%20Guidance%20(May%202019)%20.pdf

What consents might be required and when

Abbreviations used:

AE	Adverse event (including adverse reactions, product complaints, special reporting situations)
MAH	Marketing authorisation holder
MR	Market research
PV	Pharmacovigilance

Before fieldwork – at recruitment	
Consent	***Explanation***
To participate in MR	*Consent means any freely given, specific, informed and unambiguous indication of a participant's wishes by a statement or by a clear affirmative action, which signifies agreement to the processing of their personal data.* MRS Code of Conduct, 2023
To data processing for the purpose of MR	*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.* General Data Protection Regulation, Article 4
To process personal data not available in public domain	To process personal data that's not freely available in the public domain (e.g. to use a list of detailed doctors for sampling provided by the commissioning client company), the list holder must have a lawful basis for this, and consent could be the lawful basis used.
To interview a child	Consent must be given by the child's adult guardian to approach a child to ask them to participate in market research. If the child agrees to participate, they must give explicit consent.
To install and use software	To install and use software, such as an app to gather personal data, the individual must be informed of the purpose of the software, the type of data it collects and any impact it will have on the device's functioning or performance e.g. reducing battery life and consent to this.
To add individuals to an influencer mapping exercise	To collect individuals' personal data for an influencer mapping exercise, there must be a lawful basis for the data processing, the lawful basis could be consent although this may not be practical and another basis, such as legitimate interests could be used.

For the agency to observe or record non-anonymised fieldwork for analysis purposes	Even if it's only for analysis by the agency acting as a data processor, the BHBIA's Legal & Ethical Guidelines require that anyone being observed or recorded must be told why and who will listen to/see it (agency name) and agree to this, irrespective of how it will be viewed or recorded e.g. via one way mirror or video-streaming.
	If in doing this personal data is processed data protection requirements mean that if the agency and/or end client is a data controller they must be named. Similarly if the agency and/or end client is the source of or a recipient of the personal data they must be named. The client's identity may be disclosed at the end of the interview 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

***Before fieldwork – at recruitment** continued*	
Consent	***Explanation***
To allow the end client to observe or listen in to non-anonymised fieldwork live	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 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** - Data protection requirements mean you must name the organisation(s) viewing as part of informed consent for this purpose 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 for this.

To allow the end client to observe or listen in to non-anonymised fieldwork <u>after</u> fieldwork	**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

An example to illustrate data protection requirements when fieldwork is recorded and consent is sought for viewing by the end client:

- An end client (a pharmaceutical company) commissions MR and is a data controller
- A MR agency designs the MR, moderates a series of group discussions and is a data controller
- A fieldwork agency recruits the groups and is a data processor

If the end client wants to view non-anonymised fieldwork via video-streaming to their offices:

- <u>live</u> – the end client must be named before fieldwork begins and any personal data is transferred, irrespective of any concerns about whether this would impact the integrity of the MR findings
- <u>after fieldwork has taken place</u> – the end client may be named at the end of fieldwork before any personal data is shared with the end client if there is a genuine concern that identifying the end client would impact the integrity of the MR findings

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During fieldwork - at the end of the interview	
The following consents may be secured at the end of the interview as consent for these tasks is not essential to participation in the MR. These tasks can be considered separate processing operations.	
Consent	***Explanation***
To forward personal data in an AE report	If personal data is collected whilst an adverse event report is being compiled, consent to forward that personal data to the MAH's PV department for possible AE follow-up is required.
To forward personal data if disclosure is required	ABPI Disclosure UK requirements mean that incentives paid to individual HCPs participating in MR must be disclosed by client companies if the client company knows the identity of the HCPs. HCPs must give their consent for their personal data to be disclosed (if they don't anonymised information is disclosed).
To add individuals to a database for a non-MR purpose	If data originally processed for MR is to be processed for a second and non-market research process, separate consent for this is required. MR must be clearly separated and distinguished from non-MR purposes.
To re-contact a respondent after fieldwork	To re-contact a respondent after fieldwork, their consent for this must be obtained during recruitment or fieldwork. Respondents must be told why they might be re-contacted and who would contact them (organisation and roles, not names).
To keep respondent details on file for future MR	To keep respondent details on file to contact them about taking part in future MR, respondents must agree to being re-contacted and to their personal data being held on file for this purpose.
To use non-anonymised MR output for non-MR purpose	If non-anonymised MR output is to be used for a non-MR purpose e.g. film footage showing respondents faces taken from a group discussion is to be included within a training film, consent for the non-MR use of the output is required.

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British Healthcare Business Intelligence Association
St James House, Vicar Lane, Sheffield, S1 2EX
t: 01727 896085 • admin@bhbia.org.uk • www.bhbia.org.uk
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