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**Legal and Ethical Guidelines**

**for Healthcare Market Research**

**Pro Formas**

February 2024

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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. We do expect to update our guidance on the GDPR as more information becomes available.

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

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| **Recruitment Script Template** |
| **This pro forma will need to be tailored to the project and the medium (face to face, telephone, online). It has been designed to encourage a simple, concise and consistent approach to recruitment.**  |
| My name is ***<name>*** from ***<company name>,*** an independent ***<company type>.*** We are conducting market research on behalf of a ***<name or type of company sponsoring the MR>*** and would really value your opinion. [IF NECESSARY] We would prefer not to reveal the name of the healthcare/pharmaceutical company until the end of the interview, just in case knowing this biases any responses. Is this acceptable to you or not? YES NO IF NO, THE NAME MUST BE REVEALED BEFORE THE INTERVIEW TAKES PLACE OR THE INTERVIEW TERMINATED IF THIS IS NOT DETRIMENTAL TO THE INDIVIDUAL.The purpose of the research is to ***<purpose>*** and it will take the form of ***<interview type, duration, start time & location>.*** We will provide a payment of ***<amount>*** paid by ***<method of payment>*** at ***<time/place>.*** ***<Travel expenses will also be covered.>*** THIS INFORMATION MUST BE CLEAR AND SPECIFIC.Taking this opportunity to have your voice heard would greatly help us further our research, and your participation would be hugely appreciated. If you have any questions, please contact ***<name>*** at ***<company name>*** by email ***<email address>*** *and/*or call this number ***<telephone number>***. |
| **Privacy** |
| The research will comply with UK Data Protection law and with the British Healthcare Business Intelligence Association’s Legal & Ethical Guidelines.Any information you provide us with will be treated as confidential, it will be combined with feedback from others like yourself. You will remain anonymous unless you give permission to be identified. Your information will only be used for **<purpose 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 won’t keep any personal data you give us for longer than **<months/years>** for **<purpose>**.The ***<interview/group discussion>*** will be ***<watched as it happens through a one way mirror/audio and/or video recorded>*** for ***<purpose(s)>.*** The recording will only be available to ***<agency/company & client roles>.*** DEMONSTRABLE CONSENT FOR RECORDING MUST BE OBTAINED AND MUST BE SPECIFIC TO EACH PURPOSE, THIS MAY BE PROVIDED AT THE START OF FIELDWORK.IF DATA IS BEING TRANSFERRED TO A THIRD COUNTRY: We may need to send some of your personal data to **<third country>** because **<reason>**. We will make sure that it is kept secure at all times. |
| **AE Reporting: HCPs** |
| We are required to pass on to our client details of adverse events/product complaints pertaining to their products that are mentioned during the interview. If this happens, we will need to collect details and report the event, even if you have already done so via the MHRA's 'Yellow Card' system. You will be asked whether you consent to us passing your details to the client company’s drug safety department for their follow up, but you may choose to remain anonymous. This will have no impact on the confidentiality and anonymity associated with the interview itself. |
| **AE Reporting: Non-HCP –** **patient, caregiver or consumer** |
| We are required to pass on to the sponsoring client any details of side effects or product complaints relating to their products that are mentioned during the interview. This is to help them learn more about the safety of their medicines/devices. If this happens, we will need to collect details and report the side effects or product complaint. You will be asked if you give permission for us to pass your contact details to the company’s drug safety department for them to follow up. This will have no impact on the confidentiality and anonymity associated with the interview itself. |

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

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| **Recruitment Agreement** |
| Project Title:  | Project No |
| **Nature of Project** |
| Subject and purpose of MR Study:  |
| Methodology and Approach |
| **Fieldwork** |
| Location: (If online or telephone, please state this) | Duration: |
| Date: | Start Time: |
| **Reimbursement** |
| Type: (e.g. cash or vouchers etc.) | Amount: |
| **Agreement and Signature** |
| By signing below/clicking on the box below/returning this email (AMEND AS APPROPRIATE)I consent to **<agency name>** collecting and using the information about me that I voluntarily provide for the purposes of market research YES NO I have read, understand and agree to the terms described above. YES NO OTHER CONSENTS MAY NEED TO BE ADDED e.g. consent to install and use software |
| Signature:  | Name (please print) |
| **Thank you for agreeing to participate in this market research.** |

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

* Legal grounds for Data Processing
* Consents for Market Research, What is required and when

Available at <https://www.bhbia.org.uk/guidelines-and-legislation/privacy-data>

Pro Forma 3 – Disclosure

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| **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 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 the sponsoring company’s 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 healthcare/pharmaceutical company that will receive your personal data for disclosure until the end of the interview, just in case knowing this biases any responses. Is this acceptable to you or not? YES NO You may change your mind at any time. For more information about your rights please see the privacy notice, it is available at **<privacy notice location>** |
| **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 pharmaceutical company that commissioned the market research so that they can fulfil their disclosure reporting obligations. We will share your personal data under the sponsoring company’s ‘legitimate interest’ i.e. the sponsor has a legally valid reason for this, it allows us to meet ABPI disclosure obligations, and the sponsor has carefully balanced your individual rights against this need. For more information on legitimate interests please click [LINK TO PRIVACY NOTICE ]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 Pharmaceutical Industry and the UK Data Protection Act 2018, [By signing below/clicking on the box/returning this email]:* 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

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| **Receipt of Reimbursement** |
| Project Title:  | Project No |
| Agency: | Agency Contact: |
| **Fieldwork** |
| Date of receipt of reimbursement: | Start Time: |
| Location: (If online or telephone, please state this) | Duration: |
| **Reimbursement** |
| Reimbursement Type: (e.g. cash or vouchers etc.) | Reimbursement Amount: |
| **Declaration** |
| I confirm that the information I have given during the course of this interview/group discussion was correct and represents my views on the subject matter. I confirm that I have received the reimbursement detailed above in appreciation for my time and contribution to the project. |
| **Signature** |
| Signature: | Name (please print) |

Pro Forma 5 – Sales Aid Testing

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| **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 a sales aid study involving a ‘mock’ detail conducted for MR purposes only
* The information that I shall see may or may not be in its final form
* The information that I shall see is confidential, I will not disclose it to anyone else
* Anything said within the mock detail does not constitute a commitment
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| **Signature** |
| Signature: | Name (please print) |

Pro Forma 6 – Respondent Permission Allowing Client Access to Fieldwork

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| **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 company that commissioned this market research study(name of recipient organisation(s) may or may not be required will:DELETE AS APPROPRIATE* Watch through a one way mirror (watching organisations do not need to be named) but type of organisation(s) should be specified
* Listen to an audio recording at their offices (organisations listening in may or may not need to be named depending on whether audio information is considered personal data or not)
* Watch a video recording at their offices (watching organisation(s) must be named but naming may be delayed until the end of the interview if viewing is not live)

I understand that the purpose(s) of the company having access is:The people in the company who will listen to or view the recordings will be in the following functions/roles: I understand that all those listening, watching or viewing the recording must respect the confidentiality of all information exchanged in market research interviews/groups and that no sales approaches will ever be made to me as a consequence of the company having this access.I understand that I can withdraw my consent at any stage.IF APPROPRIATE We would prefer not to reveal the name of the healthcare/pharmaceutical company until the end of the interview, just in case knowing this affects any responses. Is this acceptable to you or not? YES NO  |
| **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 <https://www.bhbia.org.uk/guidelines-and-legislation/privacy-data>

Pro Forma 7 – Client Agreement to Safeguard Confidentiality of Recordings

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| **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 client company name>** I can confirm that the recording(s) of MR fieldwork from the above study will only be used for the following purpose(s):The only people in the company who will listen to or view the recordings will be in the following functions/roles: And the recording(s) will be in the secure care of:On behalf of the commissioning client company I can confirm that:* Those listening to or viewing the recording will respect the confidentiality of all information exchanged in 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.
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| **Signature** |
| I have read, understand and agree to the terms detailed above. |
| Company Signature: | Name (please print) |
| Agency Signature: | Name (please print) |

Pro Forma 8 – Observer Agreement

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| **Observer Agreement** |
| **Project Details** |
| Project Title:  | Project No: |
| Agency: | Agency Contact: |
| Location of Fieldwork:  | Date of Fieldwork: |
| Time of Fieldwork: |
| **Declaration** |
| I understand that I must be familiar with and adhere to the BHBIA’s Legal and Ethical Observers’ Guidelines.Client 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 attendee must also withdraw from observing. However, if respondents are made fully aware of the presence of an observer known to them, and give explicit consent for that individual to observe then that person may remain at the session, care should be taken that the respondents are completely comfortable if ‘put on the spot’ in this way.Observers must respect the confidentiality of all information exchanged in MR interviews/groups. You 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.
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| **Signature** |
| I have read, understand and agree to the terms detailed above. |
| Signature: | Name (please print) |

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