Guidelines for Patient Research

BHBIA ETHICS & COMPLIANCE | Quick Guide

This quick guide covers the key BHBIA guidelines for primary research conducted with patients. It highlights important points to be aware of when working with patients rather than healthcare professionals. These points are in addition to the steps you should take when undertaking research with any participant. It covers online, telephone, face to face, ethnographic research, and research with vulnerable persons and children.

Recruiting patients

- Patients can be recruited from a number of sources e.g. lists or databases or via healthcare professionals.
- Doctors may invite patients to take part in a study or pass on agency questionnaires to the patients. 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

Reimbursing patients

- For patients and members of the public remuneration should be reasonable and in line with fair market value agreed with sponsoring 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.
- In the case of children and young persons, you should ensure incentives are suitable for their age and appropriate to the market research (MR) task. If the incentive is for a child, you must inform the responsible adult of its nature and value when you ask for consent.
- Disclosure reporting requirements apply to patients as well as healthcare professionals (if the identities of the patients taking part in the MR are known to the commissioning pharmaceutical company) however unlike HCPs, disclosure of patient payments may be aggregated.

Consent

- You must obtain written agreement from all patients on the subject and purpose of the MR and the reimbursement offered.
- As for all participants in research, you must obtain consent from patients to hold their personal details. Personal data that includes health information is classified as 'special category' personal data and is subject to more demanding data protection requirements. Explicit consent for its use is required and higher standards of protection and security would be expected.
- In the case of a child (in research terms, a 'child' is a minor i.e. 15 years old or under. A 'young person' is 16 or 17 years old), you must obtain and verify informed consent from the responsible adult before asking the child. A child must have their own opportunity to agree or decline to take part, and if they agree, they must give explicit consent.

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Keeping you informed about changes in the UK legal ethical environment.

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Designing Fieldwork

- When researching any medical treatments with patients, you must not raise unfounded hopes, mislead about a product's safety, encourage them to ask their doctor to prescribe a product, or offer advice on a therapy area.
- When you need to discuss a sensitive topic, you must make sure patients know about the topic and let them know they don't need to answer all the questions and can withdraw at any point in the recruitment or interview process.
- If you need to include vulnerable patients (those who could be more susceptible than normal to physical or mental stress brought on by the research process) in your research, you must take reasonable steps to assess, identify and consider their particular needs. Vulnerable individuals must be capable of making informed decisions and not unfairly pressured to cooperate. You should consider some special conditions and contingency planning for these interviews. For instance:
    - 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.
- 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.
- For online research – when you know that patients may include children, you must first ask 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.

Further Information

For further detail on all guidelines please see the BHBIA Legal & Ethical Guidelines for Healthcare Market Research at www.bhbia.org.uk/guidelines-and-legislation/legal-and-ethical-guidelines upon which the Quick Guide is based.

If you have any queries about this Quick Guide or the BHBIA Legal & Ethical Guidelines for Healthcare Market Research, please visit **www.bhbia.org.uk** and submit your query via **'My BHBIA'** Please note: this ad hoc advisory service is available to full BHBIA members only.

Disclaimer

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

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