BHBIA
ETHICS & COMPLIANCE

Guidance

What is Research Ethics Committee Approval and when is it needed?

Purpose

To introduce the concept of 'ethics committee approval' and distinguish between Market Research and Health Research and provide some background on why Research Ethics Committee (REC) approval is not a requirement when undertaking Market Research.

What is REC?

The UK Health Research Authority (HRA) and the Devolved Administrations provide a Research Ethics Service so that research proposals relating to their areas of responsibility can be reviewed by a Research Ethics Committee (REC).

A research ethics committee is a group of people appointed to review research proposals to assess formally if the research is ethical. This means the research must conform to recognised ethical standards, which includes respecting the dignity, rights, safety and well-being of the people who take part[1].

RECs act primarily in the interests of research participants. RECs also take into account the interests and safety of the researchers, as well as the public interest in reliable evidence affecting health and social care and enable ethical and worthwhile research of benefit to participants or to science and society[1].

Research Ethics Committees and their approval process varies from country to country with some having an IRB (Independent Review Board, or Institutional Review Board) or EC (Ethics Committee), all however providing a similar function.

What is Market Research?

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.

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 drug safety surveillance.

Market Research (as defined by the BHBIA) attempts to generate understanding and knowledge of a marketplace 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.

Key distinctions between Healthcare MR and Health Research are provided in the following table:

	Market Research	**Health Research**
Purpose	Commercial focus/purpose (market behaviour and opportunities) – designed to inform business decision making	Clinical or medical focus/purpose (e.g., safety, efficacy, pharmacokinetics, quality of life) – designed to advance science, the treatment of disease and improve patient outcomes
Endpoints	Clinical endpoints not required, no requirement to generate scientifically sound evidence	Clinical endpoints required, goal is to generate scientifically sound evidence
Protocol	Written protocol not essential	Written protocol as required
Method	Epidemiological methods not required	Epidemiological methods must be used to design the study and analyse the data
Remuneration	Participants are generally financially incentivised	Participants are not generally incentivised

Management	Managed by commissioning company's commercial teams, generally marketing	Managed by commissioning company's scientific/medical service or individual's medical/academic supervisor
Approval	Does not require REC approval	Normally requires REC approval
Publication	Unlikely	Likely

EphMRA provides a detailed overview of the differences between market research (MR), non-interventional studies (NIS) and patient support programmes (PSP) within its Code of Conduct (section 1, 1.3) available on the EphMRA website: https://www.ephmra.org/sites/default/files/2022-08/EPHMRA%202022%20Code%20of%20Conduct.pdf

Research Ethics Committee approval is not a requirement for Market Research

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.

2.3.13 RECs are not expected to consider applications in respect of activities that are not research, for example clinical or other non-financial audit, service evaluation and public health surveillance.

Some Frequently Asked Questions

Q: I want to publish some market research however the publication requires REC approval. Can I get retrospective approval?
A: Approval should be granted prior to research execution. If not, the board could deem the study to be 'unethical' or any study already carried out invalid. It is also very rare for an IRB/EC/REC to accept retrospective applications.

Q: Do I need REC approval to publish market research that is being used in a publication?
A: Although REC approval is not required for market research there are some publications who will only publish a submission that has received Ethics approval.

This approval could be granted by REC, IRB or other EC bodies. We would recommend checking the submission requirements of the intended publications.

Q: I am doing some Market Research with patients. Does this require REC approval?
A: Not necessarily, REC approval is not required when conducting market research with patients (see distinction between market research vs health research which requires REC approval as outlined earlier in document).

Q: I am using patient records for a market research project, does this require REC approval?
A: This would depend on the purpose of the study or if this is required by law, e.g. if the study requires approval under the Mental Capacity Acts. Patient records can be used for market research if the data is anonymous or if the patient gives explicit consent to use their non-anonymised data.

Q: Does the information submitted for REC review remain confidential in the UK?
A: The HRA publish details about each research study reviewed by a REC in the UK on their research summaries pages. The information is taken from the IRAS (Integrated Research Application System) application reviewed by the REC.

Q: Do Market Research projects commissioned to support market access submissions e.g. NICE require REC approval?
A: MR does not require REC approval, however if the study falls under the definition of health research it may require REC review.

Q: How long does REC approval take?
A: This can vary. The UK REC is required to give an ethical opinion on an application within 60 days of the receipt of a valid application if no further information is required. US IRB approvals are generally quicker.

Q: How much does it cost to request REC approval?
A: UK REC application and approval is free whilst the price of IRB approvals will differ depending on the approval board.

Q: Is a study submitted for REC approval subject to further monitoring or checks during recruitment, fielding, analysis, and reporting?
A: Typically, there is no monitoring, inspection, audit, source data verification, as a result of REC approval. The REC examines a study based on submitted documents with the focus being ethical considerations. If there are changes during the study, protocol deviation or study amendments, resubmission to IRB/REC may be required. Applicants should check on the individual IRB/REC procedure.

Sources and references for further reading

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

Governance Arrangements for research ethics committees: https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/GAfREC_Final_v2.1_July_2021_Final.pdf

Ephmra 2022 Code of Conduct: https://www.ephmra.org/sites/default/files/2022-08/EPHMRA%202022%20Code%20of%20Conduct.pdf

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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