MRIA CODE OF CONDUCT FOR MARKET AND SOCIAL MEDIA RESEARCH

Appendix "O"

GUIDELINE ON PHARMACEUTICAL RESEARCH IN CANADA

(Adopted from the European Pharmaceutical Marketing Research Association (EphMRA) Code of Conduct)

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1 Introduction

1.1 Purpose, Scope, and Sources

The purpose of the Canadian Pharmaceutical (Pharma) Code is to foster public confidence and to demonstrate research practitioners' recognition of their ethical and professional responsibilities in carrying out pharma marketing research studies. This Code is modeled after, and adopted from, the European Pharmaceutical Marketing Research Association (EphMRA) Code of Conduct. Also, this Code is based on the following Canadian laws: Personal Information Protection and Electronic Documents Act (PIPEDA), – Personal Health Information Protection Act (PHIPA) Ontario (ON), Personal Information Protection Act (PIPA) British Columbia (BC), PIPA Alberta (AB), and Act Respecting The Protection Of Personal Information In The Private Sector (Privacy Law of Quebec) Quebec (QC).

2 Principles of the Code of Conduct

The MRIA Code of Conduct for marketing research studies is governed by the sixteen Articles in the MRIA Code of Conduct. The Articles are listed in the introduction of the Code.

3 What Constitutes Market Research - Minimum Standard

1. Market research is the systematic gathering and interpretation of information about individuals or organizations using the statistical and analytical methods and techniques of the applied social sciences to gain insight or support decision making.

2. Market research (as defined above) relating to market or consumer behaviour of the sort that pharmaceutical companies routinely commission, whether involving healthcare professionals, patients, other care providers, or members of the public does not require Clinical Research Ethics Committee or Independent Review Board approval.

3. The identity of respondents will not be revealed to the user of the information without explicit consent, and no sales approach will be made to them as a direct result of their having provided information.

4. 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 an organization, e.g., providing expert advice on new drugs and opportunities. If the advisory board is recruited and operated as market research - meeting the definition above - then it is market research.

4 Differentiating Marketing Research studies from other research studies

Market research is defined by the objective(s) and the approach, not by the title of the work or those involved in it. Consequently, the Pharma Code of Conduct includes areas such as digital listening (the use of social media content for market research), the use of observational/ethnographic approaches and work carried out online via mobile devices. The following table distinguishes between the characteristics of market research, patient support programmes, and non-interventional studies.

Difference between Market Research (MR), Patient Support Programmes (PSP) and Non-interventional Studies (NIS). Yes(Y), No (N). (From the EPHMRA Code of Conduct)

	MR	PSP	NIS
Information gathering tool	Y	N	Y
Patient or carer service	N	Y	N
Participants remain anonymous	Y	N	Y or N
Commercial focus/purpose	Y	Y	N
Clinical focus/purpose	N	N	Y
Direct patient benefit	N	Y	N
Promotional tool	N	Y	N
Directly impacts clinical care	N	Y	N
Pooled processing of information generated	Y	N	Y
Participants are generally financially incentivized	Y	N	N
Impacts patient directly and immediately	N	Y	N
Generally generates scientifically significant information	N	N	Y
Requires clinical research ethics committee approval	N	N	Y
Can be prospective or retrospective	Y	N	Y
Always involves marketed product	N	Y	Y
Managed by company's scientific service (rather than commercial)	N	Y or N	Y
Generally includes patient prescribed a company's medicinal product in the usual manner	N	Y	Y
Epidemiological methods must be used to design the study and analyze data	N	N	Y

5 Conducting Marketing Research and Non-Research Activities

1. Research activities must be kept separate from non-research activities, and data gathered during the research study must not be used for list building. The researcher must not engage in sugging, which is selling anything in the course of conducting a survey.

2. The client is the commissioning company head office or regional office or local affiliate/office; these may be pharmaceutical medicine manufacturers, producers of devices, over-the-counter medicines, or other organizations.

3. Agency is the full-service market research agency, fieldwork agency, independent recruiter, freelance researcher or interviewer; one of these may be the main contractor or a sub-contractor. Agencies may also include marketing or management consultancies, public relations (PR) or advertising companies that run market research studies.

4. Sub-contractors are bound by the same legal and ethical requirements as the main contractor.

5. For data protection purposes, original holders of personal data can, if contractually bound, pass personal data to other parties without seeking the explicit consent of the individuals as long as the data is being used for a purpose for which the original holder has a lawful basis to process the personal data, such as the consent of the individual.

6 Data Protection and Privacy – Minimum Standard

1. Article 7 – Data Protection and Privacy, of the MRIA Code of Conduct, provides the requirement for members to follow when collecting respondents' personally identifiable information (PII). Personal data is protected by the provisions of PIPEDA, PHIPA (ON), PIPA (AB & BC), and the Privacy Law of Quebec.

2. Canadian Privacy Laws cover the collection of data relating to an identifiable person. Also, the MRIA Privacy Handbook (for members only) addresses the privacy concerns as they relate to marketing research studies.

3. Personal data covered by Canadian Privacy Laws includes data "be it alphabetical, numerical, graphical, photographic or acoustic."

4. Personal data may be a single piece of information or a series of pieces of information including other information or data sets available to the holder, which together would allow identification of an individual.

5. Respondents must be made aware that they can ask at any time to know what personal data about them is currently being held and for these to be amended or destroyed.

7 Security – Data Protection and PIPEDA - Minimum Standard

An organization must clearly identify a person within that organization who is their in-house privacy compliance officer. This individual will be responsible for ensuring that the organization is in continual compliance with the Act.

1. Adequate precautions must be taken to protect personal data, any sensitive data, and confidential information against unauthorized access.

2. Researchers are responsible for the safe handling, processing, storage, and disposal of market research and personal contact data.

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8 Respondents' Rights to Their Data

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9 Informed Consent – Minimum Standard

1. Researchers must ensure that respondents give their informed consent before information is collected from them.

2. Informed consent guarantees respondents the right not to participate and the right to withdraw from the interview at any time.

3. Information detailing an individual's physical or mental health is classified as 'sensitive personal data' and requires explicit consent for its use.

10 Confidentiality & Anonymity – Minimum Standard

1. Researchers must make it clear to respondents that all personal data collected during a market research project will be treated confidentially and is purely for market research. Only in instances where an adverse event reporting is required will a member's personal data be used without the separate consent of the respondent.

2. Respondents' anonymity must be strictly preserved.

3. Researchers must ensure that information identifying the respondent is not passed to the client without the respondent's explicit consent.

4. Withholding a respondent's name is not necessarily sufficient to protect their anonymity especially when respondents belong to small high profile universes.

11 Waiving Right to Confidentiality – Best Practice

1. The respondents' right to confidentiality can be waived by the respondents if specific consent has been sought and granted providing the respondents have been made aware of:
    I. To whom they will be identified
    II. What will happen to the information they give
    III. If anything will happen to them as a result of this waiver

12 Key Research Stages - Before Fieldwork

12.1 Preparing the Sample – Minimum Standard

1. The size of the sample must be appropriate to meet the market research objectives. If the sample size is unnecessarily large, the market research may be considered a promotional vehicle.

2. Researchers should manage and monitor the frequency with which potential respondents participate in market research and try to avoid over-researching individuals.

3. Lists that are drawn from sources readily available within the public domain do not generally require the consent of the individuals listed to have their personal details held.

4. Respondents that have chosen to opt-out of, or not be contacted for market research must be excluded.

5. If it is requested, the source of the list must be revealed to potential respondent(s) at an appropriate point in the interview.

12.2 Recruitment – Minimum Standard

1. Physicians may act as intermediaries to recruit patients by inviting patients to take part or passing on questionnaires on behalf of the agency. However, they must comply with the following:
   I. Ensure that patients understand that their participation is voluntary
   II. Do not disclose the patient's identity to the agency without the patients' consent

2. At recruitment respondents must be told:
   I. Type of organization sponsoring the market research
   II. Subject and the purpose of the market research
   III. Contact details
   IV. Length of the interview
   V. Their rights
   VI. What will happen to their data and how it will be used
   VII. Incentive offered

3. The physicians must disclose their intermediary status to the respondents, the purpose for which the data collected will be used, and also, they must get the consent of each respondent before passing on their personally identifiable information to the market researcher.

4. Healthcare professionals must be informed of the need to report adverse events uncovered during the study where this need exists.

12.3 Incentives - Minimum Standard

1. An incentive is a monetary or non-monetary offering to a respondent to encourage participation in a market research study.
   I. Dependent only on the correct completion of a questionnaire/interview
   II. Appropriate to the respondent type – Appropriate to the task(s).

2. Respondents must be clearly informed:
   I. Who will administer the incentive
   II. What the incentive will be

III. When the participant will receive the incentive
IV. If any conditions are attached

13 Key Research Stages - During Fieldwork

13.1 Information to Be Communicated to Respondents at the Start of Fieldwork – Best Practice

1. The following information should be provided to respondents at the start of fieldwork, even though much of this information will have been communicated at recruitment:
    I. Details about the true nature and purposes of the study
    II. What will happen to the information they give
    III. Details of any viewing or recording
    IV. Country-specific requirements for adverse event reporting

13.2 Questionnaire and Question Design - Minimum Standards

1. Researchers must take reasonable steps to ensure that:
    I. Questions are suitable for the purpose and client has been advised accordingly
    II. Questionnaire design and content are appropriate for the audience being researched
    III. Respondents can answer the questions in a way that reflects the view they want to express, including “don’t know/prefer not to say” where appropriate
    IV. Respondents are not led towards a particular answer
    V. Personal data collected is relevant and not excessive

14 Sensitive Topics – Minimum Standard

1. When sensitive topics are to be discussed, the respondent must be made fully aware of:
    I. The topic of discussion before the interview
    II. The fact that they need not answer all of the questions posed
    III. Their right to withdraw at any point in the recruitment or interview process

15 Stimulus Material – Minimum Standard

1. Stimulus material must be suitable for the purpose.

2. Pharmaceutical industry codes of practice generally require that information claims and comparisons be accurate, balanced, fair, objective, and unambiguous, be an up-to-date evaluation of all the evidence, and should not mislead either directly or by implication, by distortion, exaggeration or undue emphasis – the same is expected of stimulus material.

3. Stimulus material includes any material shown during fieldwork to elicit a response.

16 Consents Required – Minimum Standard

1. Respondents must be made aware at the time of recruitment if they will be recorded or observed and why it is proposed.

2. In instances of telephone interviews, the respondents' verbal consent is acceptable, and Respondents' written consent for audio or video recording should be obtained at the beginning of the interview before recording commences.

17 Adverse Event Reporting – Minimum Standard

1. Any untoward medical occurrence in a patient administered a medicinal product, which does not necessarily have a causal relationship to treatment can be considered an adverse event. This can be any unfavourable and unintended sign, symptom or disease associated with the use of a product regardless of whether there is a causal relationship. Adverse events can include:
    I. Product complaints (defective equipment)
    II. Maladministration/medication errors
    III. Under or overdose, whether accidental or intentional
    IV. Accidental Exposure
    V. Abuse / Misuse of the product (including 'off-label' use)
    VI. Drug-drug interaction, drug-food interaction
    VII. Events related to withdrawal of the product
    VIII. Suspected transmission of infectious agent
    IX. Failure of the expected action (Lack of Efficacy)
    X. Identification of a counterfeit medicine
    XI. Exposure during pregnancy or breastfeeding

2. Adverse Events must be reported to the Drug Safety Department of the pharmaceutical manufacturer within one (1) business day (or 24 hours if so specified).

3. Also, details of the adverse reactions that meet the qualifying and minimum reporting criteria should be forwarded to the nominated contact within the market authorization holder that commissioned the market research.

4. Consumers/patients/respondents and health professionals can also report adverse reactions to the Canada Vigilance Program. Website: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html Online form: https://hpr-rps.hres.ca/static/content/form-formule.php?lang=en

18 Storage and Security - Minimum Standard

1. Respondents must consent to the storage of their personal data for future use.

2. Personal data must be destroyed as soon as the purpose of the study is redundant.

3. The data disposal method should be appropriate to the sensitivity and confidentiality of the data.

19 Reporting Market Research –Minimum Standard

1. Researchers must take reasonable steps to ensure that:
    I. Interpretation and conclusions are adequately supported by the research findings, with an explanation as to which data support the interpretation.
    II. The detail necessary to assess the validity of findings is available, and that data tables include sufficient information to enable reasonable assessment of the validity of the results.

2. Reports and presentations must accurately reflect the findings of the research. They must reflect the researcher's interpretations and conclusions and distinguish between factual reporting of data and a researcher's interpretation.

20 Respondents' Rights by Research Approach

20.1 Face-to-Face Methodology – Best Practice

1. The name of the agency for which the interviewer is working should be given verbally, and it is good practice for the interviewer to give his/her name to the respondent.

21 Telephone Methodology - Best Practice

1. To gain the trust of respondents without having the benefit of face-to-face contact, the interviewer should give the name of the agency that he/she represents and should give their name or an agreed contact name.

2. Do-not-call lists specific to market research must be respected.

3. Researchers should take special care about respondents' safety and privacy when contacting respondents via mobile phones.

22 Ethnographic/Observational Approaches – Best Practice

1. Observational or ethnographic research is defined as any research form which relies significantly upon the observation of human behaviour as one of its data sources, whether respondents are openly observed (participant observation) or covertly or indirectly observed (non-participant).

2. When conducting ethnographic market research, researchers are advised to:
    I. Inform respondents of the overall reasons for the observation of their behaviour.
    II. Clarify in writing and gain documented agreement as to the precise nature of the research and the responsibilities of each party.
    III. Inform respondents of the extended nature of ethnographic research at the point of recruitment before they agree to participate.
    IV. Timings should be clear.
    V. Inform respondents at recruitment of any activities they will be asked to undertake.
    VI. Use language that is understandable.
    VII. Explain significant factors that could influence the person's willingness to participate.
    VIII. Guard against unwarranted intrusion.

23 Online & Mobile Devices

23.1 Privacy and Data Protection – Minimum Standard

Researchers must post a privacy policy statement. The statement should be easy to find, easy to use and comprehensible, including by children when appropriate. 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.

1. The researcher can provide links to data protection policy, privacy policy or cookie consent statements at the start of the market research study. This information will ensure that, should respondents fail to complete the exercise for any reason, their rights are protected.

2. When emails are sent in batches, respondents' email addresses must be kept confidential, so for instance, blind copying should be used. Blind Carbon Copy may be accessed and could reveal the identity of the other recipients. The mail should be sent to each recipient individually.

23.2 Protecting Personal and Company Data – Minimum Standard

1. Researchers must use adequate technologies to protect personal and sensitive data when collected, transmitted or stored on websites or servers.

2. Cookies store specific information about online browsing. Canadian Anti-Spam Legislation (CASL) states that a cookie can be stored on a user's computer, or accessed from that computer, only if the user "has given his or her consent, having been provided with clear and comprehensive information."

3. Clients should be made aware of the potential risks of using confidential information in online or mobile surveys. Agencies should be required to implement strict security procedures.

4. Confidential information, even if protected by non-disclosure agreements, is easily printed/stored/forwarded and practically impossible to remove from circulation.

24 Disclosing List Sources from Website Registration Databases – Minimum Standard

1. Where lists are used for sample selection, the source of the list must be disclosed. Where these are derived from website registration databases, researchers must check that registration was voluntary and that the data is current.

25 Use of Unsolicited Emails for Recruitment - Minimum Standard

1. Researchers must avoid intruding unnecessarily on the privacy of respondents. ESOMAR advises that unsolicited email approaches to potential respondents should not be made even in countries where this is permitted by law unless individuals have a reasonable expectation that they may be contacted for research.

2. Canada's Anti-Spam Legislation (CASL) restricts the use of unsolicited email unless there is prior consent. Each email must have prior consent, be it expressed or implied, identification of the sender, and an unsubscribe button.

3. MRIA Code of Conduct – Appendix B - Mobile Marketing Research-2.2 4th paragraph - In general, researchers must not make unsolicited email approaches to potential participants, unless individuals have a reasonable expectation that they may be contacted for research due to a pre-existing relationship with a company or organization. Where an email approach is undertaken, researchers should plainly state the purpose of the email in the subject heading and keep the total message as brief as possible. Similar guidelines apply to other forms of electronic messaging.

26 Using Identification and Tracking Technologies/Software – Minimum Standard

1. Respondents must always be told at the first opportunity when software is being used to collect information about them, and they must also be told:
    I. The reason for the use of the tracking device or soft
    II. If the data subject's information is to be shared
    III. That they can turn them off or remove them

2. Explicit consent for downloading software to be used for market research purposes must be sought, and a means provided to address questions.

27 Online Access Panels – Minimum Standard

1. Panel members must be made aware that they are members of a panel and should be reminded of this at regular intervals. Access panels are a sample database of potential respondents who declare that they are willing to receive invitations to participate in future online interviews. At recruitment, potential panel members must be told that their personal data may be stored for further market research.

28 Social Media - Best Practice

1. Social media platforms have terms and conditions which all users must agree to follow before gaining access to the platform. Many service providers include intellectual property rights clauses that prohibit copying of material without consent. Researchers should ensure that they abide by the terms and conditions to which they agreed.

29 Respondents' Rights by Respondent Type

29.1 Patients - Best Practice

1. When researching existing or future potential medical treatments with patients, care should be taken not to:
    I. Raise unfounded hopes of treatment of specific medical problems.
    II. Mislead respondents about the safety of a product.
    III. Encourage members of the public/patients to ask their doctor to prescribe a product.
    IV. Offer advice on the specific therapy area under discussion.

30 Vulnerable Respondents – Best Practice

1. Vulnerable respondents are those who, for whatever reason, could be more susceptible than normal to physical or mental stress induced by the research process. Also, individuals who are of legal age, and are unable to make certain decisions independent of a legal guardian.

2. If the respondents are considered vulnerable, then the following questions should be considered:
    I. Is the market research justifiable?
    II. Is the nature of interview/tasks involved appropriate?
    III. Should a caregiver be present or on hand if required?
    IV. Is additional time or the provision of breaks needed?

31 Children and Young People – Minimum Standard

1. Consent from the parent or legal guardian is required to ask the child whether they will participate.

2. Consent of a parent or legal guardian must be obtained before interviewing a child under the age of fourteen (14).

3. Consent from the children must also be given; the children must have their opportunity to agree or decline to participate.

4. It is recommended that the consent of a parent or legal guardian be obtained when contacting a young person (14-17) by telephone or online. However, when meeting with a young person parental consent is required.

5. Personal information relating to other people must not be collected from children unless it is to be used to gain consent from a parent/responsible adult.

32 Opinion Leaders, Clinical Trial Investigators and Advisory Board Members - Best Practice

1. When recruiting respondents that have a pre-existing relationship with the company, it is acceptable for the initial invitation to participate in the market research to come from the client's company.

33 Complaints and Grievance Procedure – Best Practice

1. Infractions, breaches of the Code of Conduct, and complaints will be investigated by the MRIA as outlined in "Appendix "A" Complaints Adjudication Procedure. Appropriate action will be taken based on the standards outlined in the Adjudication Procedures.

References

1. European Pharmaceutical Marketing Research Association
2. PIPEDA
3. PHIPA (on)
4. PIPA (Alberta
5. PIPA (BC)
6. ESOMAR