

EphMRA CODE *of* CONDUCT

Log of Revisions made to EphMRA's Code of Conduct

Date of Change	Page Number	Reference	Previous wording	Revised wording (in coloured font)
Most recent listed first				
4 March 2010	6	4.4	Market research that meets the definition above, whether involving healthcare professionals, patients, carers or members of the public does not require Clinical Research Ethics Committee or Independent Review Board approval.	Market research that meets the definition above, whether involving healthcare professionals, patients, carers or members of the public does not require Clinical Research Ethics Committee or Independent Review Board approval (Institutional Review Board in the USA).
4 March 2010	7	5.6	When researchers are fulfilling their role as researchers they must not conduct other non-research activities; researchers cannot combine the collection of personal data for the dual purposes of market research and direct marketing.	When researchers are fulfilling their role as researchers they must not conduct other non-research activities without the prior informed consent of respondents .
4 March 2010	20	13.33 Paragraph 4 Bullet 3	– Unexpected lack of efficacy	– Lack of efficacy
4 March 2010	20	13.33 Paragraph 7	Adverse events that meet the four minimum reporting criteria must be reported. Each of the following four pieces of information must be present to make an event eligible for reporting: 1. An identifiable patient - identified by initials, number, date of birth, age, age group <u>or</u> sex, only one of these identifiers is required to ensure the patient is identifiable. 2. An identifiable reporter - the reporter may be identified by name/initials and address <u>or</u> qualification (e.g. doctor, nurse, patient, pharmacist). 3. At least one suspected adverse event. 4. At least one suspected active substance/medicinal product	Adverse events that meet the four minimum reporting criteria must be reported. Each of the following four pieces of information must be present to make an event eligible for reporting: 1. An identifiable patient - identified by initials, number, date of birth, age, age group <u>or</u> sex, only one of these identifiers is required to ensure the patient is identifiable. Although in the UK, pharmaceutical companies and their legal agents must now forward all adverse events that are cited in the context of any patient or group of patients, whether or not a specific identifier is present. Previously a specific identifier was required. 2. An identifiable reporter - the reporter may be identified by name/initials and address <u>or</u> qualification (e.g. doctor, nurse, patient, pharmacist). 3. At least one suspected adverse event. 4. At least one suspected active substance/medicinal product.

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4 March 2010	21	13.38 Paragraph 4	If data, especially diary data is being examined on an aggregate basis then no reporting by pharmaceutical companies or market research agencies is required. If the pharmaceutical company requests patient specific data then the pharmaceutical company will need to report any adverse events that are identified.	If data, especially diary data is being examined on an aggregate basis then no reporting by pharmaceutical companies or market research agencies is required. If the pharmaceutical company requests patient specific data then the company will need to report any adverse events that are identified except in the UK, revised UK Guidelines now require the company to forward adverse event data whether individual patient records or aggregate data are purchased.
4 March 2010	21	13.39	Collecting Adverse Event Reports in the UK – the UK ABPI/BHBIA’s Guidelines state that all organisations and individuals contracted to work on behalf of the commissioning company including market research agencies e.g. interviewers or moderators, are obliged to report adverse events. Consequently researchers have an obligation to record reportable adverse events and report these to the MAH.	Collecting Adverse Event Reports in the UK – the UK ABPI/BHBIA’s Guidelines state that all organisations and individuals contracted to work on behalf of the commissioning company including market research agencies e.g. interviewers or moderators, are obliged to report adverse events. Consequently researchers have an obligation to record reportable adverse events and report these to the MAH. Revised Adverse Event Reporting Guidelines come into force in the UK from 1 May 2010. The revisions have been incorporated into EphMRA’s Code.
4 March 2010	24	16.5	In Germany data protection laws prohibit the telephone interviews that are in any way directly linked with telephone marketing.	In Germany data protection laws prohibit the telephone interviews that are in any way directly linked with telephone marketing. For further details upon telephone interviewing in Germany see Guidelines on Telephone Surveys published by the ADM. www.adm-ev.de/index.php?id=2&L=1
4 March 2010	27	18.12	Respondents must always be told when cookies or other covert software, sometimes referred to as spyware or active agent technology is being used to collect information about them, why they are to be used and that they can turn them off or remove them. Information for respondents should allow a clear appreciation of the potential consequences of allowing the use of the cookie etc. In the UK this is a legal requirement in accordance with the Privacy and Electronic Communications Regulations. For the USA CASRO provides detailed guidelines with regard to the use of active agent technology within its Code of Standards and Ethics. www.casro.org/codeofstandards.cfm#sectionI.B.3 Aug 2009	Respondents must always be told when cookies or other covert software, sometimes referred to as spyware or active agent technology is being used to collect information about them, why they are to be used and that they can turn them off or remove them. Information for respondents should allow a clear appreciation of the potential consequences of allowing the use of the cookie etc. In the UK this is a legal requirement in accordance with the Privacy and Electronic Communications Regulations. For the USA CASRO provides detailed guidelines with regard to the use of active agent technology within its Code of Standards and Ethics. www.casro.org/codeofstandards.cfm#sectionI.B.3 Aug 2009 In Germany websites that use analytics tools must give users the chance to opt out and must not use IP addresses to build usage profiles. An IP address is considered by law to be personally identifiable information.

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14 Jan 2010	11	11.1 Paragraph 1 Bullet 4	The study does not specify any respondent remuneration (direct or indirect)	The study does not provide any respondent remuneration (direct or indirect)