

EphMRA CODE of CONDUCT

Log of Revisions made to EphMRA's Code of Conduct

Date of Change	Page Number	Revised Reference	Previous wording	Revised wording (in coloured font)
Most recent listed first				
01 Dec 2011	33	18.23 to 18.35	<p>ESOMAR has proposed the following classification of social media space:</p> <p>Public space - a place where content is contributed with the assumption that it could be read by anyone in the public and where contributors could not be surprised that it is linked to/copied/cited. Examples include many public blogs or comments left on news websites.</p> <p>Semi-public space - a place where people contribute content which although technically open to all to read, many would not expect it to be read or used by people not involved in the specific topic or conversation.</p> <p>The boundary between public and semi-public space is open to interpretation and researchers are encouraged to act with caution and regard sites as 'semi-public' if they have doubts. Examples include Facebook home pages and many niche (but open) forums/communities. It also includes all forms of open synchronous online activity e.g. open chatrooms, Twitter, etc.</p> <p>Private space - a place where most users would expect their comments to be private and which is available only to genuine community members. They are often called 'walled gardens' as they can only be accessed after the user has obtained a login and/or password, even if entry is automatic. Examples include many private forums, communities and chatrooms as well as instant messaging.</p> <p>Specific market research space - an online place specifically created for market, social and opinion research purposes where users have been informed of its function and the use to which their comments might be put. Typically (but not always) these are also private spaces. Examples include Market Research Online Communities (MROC's).</p>	<p><u>Social Media</u> Social media is defined by ESOMAR as "internet based platforms and technologies that permit users' interaction and/or facilitate the creation and exchange of user generated content." Widely used examples include:</p> <ul style="list-style-type: none"> - Online forums/discussions, communities, blogs, social networks (e.g. Facebook) - Video/photo sharing (e.g. YouTube) - Multi-person/group communication and/or collaboration platforms (e.g. Twitter)." <p>18.23 When conducting social media market research, researchers are bound by the terms and conditions attached to access of the online services. Many service providers include intellectual property rights clauses that prohibit copying of material without permission. Researchers should ensure that they abide by the terms and conditions attached to use of site content. However if permission for listening/scraping is not given, researchers can read and précis the content.</p> <p>18.24 Care must be taken to ensure that anonymous quotations are indeed anonymous and cannot be traced back to reveal their original source.</p> <p><u>Passive market research</u> i.e. digital listening, scraping</p> <p>18.25 Without the contributor's permission (obtained as part of the terms of use or directly) only anonymised data can be reported. Anonymised data must not reveal any personally identifiable information.</p> <p>18.26 No attempt must be made to identify contributors. ESOMAR states that this must be a contractual obligation if the data is</p>

ESOMAR Guideline on Social Media Research, Draft, Feb 2011

The following guidelines apply within each type of ‘space’:

Public space - may be used by researchers, although it may be necessary to ‘cloak’ comments if they could be in any way harmful to the individual (e.g. embarrassing). Cloaking means altering information so that it cannot be traced back to the contributor.

Semi-public space – researchers should not pass on any identifiable information.

Private space – market research can only take place with the consent of the service provider. Researchers should announce their presence and seek the co-operation of site participants. Researchers must gain the consent of participants to quote them and without this consent, all comments should be cloaked. Researchers must not pose as an ‘ordinary’ participant e.g. on a patient website to gather information - their role and purpose must be transparent.

Specific market research space – The same guidelines apply to these as to other forms of internet market research.

Using Social Media Space for Market Research Purposes

Space	Available for researchers	Identifiable in reports	Cloaking of verbatim quotes in reports
Public space	Yes, subject to service Terms of Use	Yes, except if might cause harm	No, only required if it might cause harm
Semi-public space	Yes, subject to service Terms of Use	No, except with user permission	More likely to be required than a public space and essential if it might cause harm
Private space	Only with permission of service	No, except with user permission	Essential unless user gives permission to cite
Market research space	Yes	Possible, subject to sign up agreement	No, only required if it might cause harm

Source: *ESOMAR Guideline on Social Media Research, Consultation Draft, Feb 2011*

passed on to the client or another researcher. If a contributor’s comments are to be made public (i.e. cannot be covered by contractual obligations) and the contributor is easily identifiable, their permission should be sought or the comment disguised or ‘masked’ appropriately.

18.27 Quotations containing personally identifiable information (PII) can only be provided to the client if the contributor has given their permission for this and it has been made clear that they will not be subject to promotion as a result of this.

18.28 In ‘private’ SM spaces (ones in which users would expect their comments to be private), researchers must seek and gain the permission of contributors to listen in/scrape comments and comments given to clients must be masked unless the contributor gives permission for their comments to be passed on verbatim. This assumes the terms and conditions have not given explicit site owner and site user permission for listening in/scraping.

Active market research i.e. engaging with participants

18.29 Permission from the site/service owners and **contributors/users** must be given.

18.30 Researchers must declare their presence, they must not represent themselves as anything other than market researchers.

18.31 Contributors must be told the identity of the research organisation, purpose of the market research, what sort of data will be collected, how their comments will be used and who will have access to it.

18.32 Contributors must be provided with contact information for the researcher or research agency.

18.33 Researchers must publish a privacy policy on their website.

18.34 Online space created specifically for MR such as MROCs must fulfil the following criteria:

- Participants must be aware of its function and the use to which their contributions might be put and that the data will be shared with the client
- Any rules for interacting must be available

				<ul style="list-style-type: none"> - Site privacy policy must be available - The personal identity of participants must be protected.
01 Dec 2011	44	Appendix	NEW ADDITION	<p>18.35 Adverse event reporting requirements are the same when market researchers use social media as a source of market research data as any other market research medium such as face to face interviews. Marketing authorisation holders and their agents have an obligation to collect and follow-up on the adverse events and product complaints associated with their products. This applies to public and private sites, passive and active approaches and to company sponsored and non-company sponsored websites.</p> <p>If a company chooses to listen-in to or ‘scrape’ from non-company sponsored sites, whether public or private (with consent) it is recommended that the listened to pages should be monitored for adverse events for the period of the listening-in activity only. There is no obligation for researchers to monitor non-company sponsored sites routinely for adverse events if they are not being used for a market research purpose.</p> <p>Further Information upon Social Media Guidelines – ESOMAR Recommendations</p> <p>Disguised Promotion</p> <p><i>“If quotes containing personally identifiable information are passed to the client, unless national provisions require stricter regulations, the following conditions must apply:</i></p> <ul style="list-style-type: none"> <i>i) the respondent has explicitly expressed this wish and/or</i> <i>ii) the respondent has given their explicit consent</i> <i>iii) on the understanding that no commercial activity will be directed at them as a direct result of their having provided information.”</i> <p>Consent and notification</p> <p><i>“If consent has not been obtained (directly or under the ToU) researchers must ensure that they report only depersonalised data from SM sources. If researchers are using automated data collection services, they are recommended to use filters and controls to remove</i></p>

				<p><i>personal identifiers such as user names, photos, links to the user’s profile, etc. Where this is not possible or they are manually collecting data from websites, their analysis must only be with depersonalised data and no attempt should be made to identify people.”</i></p> <p><i>“If depersonalized SM research data is passed on to another researcher or client, the researcher must have a contract with the recipient of the data which requires them not to attempt to use technical means to re-identify quotes or their posters and use such data for a non research purpose and to observe the ICC/ESOMAR Code and the provisions of this guideline, i.e. they will.”</i></p> <p><i>“When researchers, or their automated agents, interact directly with users within SM, they must also convey to them their purpose, role and how they will use any comments. They must also seek permission from users and the service owners or their representatives to conduct their work. Furthermore when taking part, researchers must ensure they do not misrepresent themselves as a genuine member of that SM space.”</i></p> <p><i>“When researchers, or their automated agents, are working in SM spaces, they must provide an email address and a telephone number and/or mail address to facilitate contact and verification. For additional transparency, and to meet data collection notice requirements, researchers must publish a privacy policy on their website.”</i></p> <p>Protecting identifiable data</p> <p><i>“SM platforms offer many opportunities to view personally identifiable data. Data cannot always be 100% anonymised on the internet by merely removing the username and linked URL from the comment. Therefore if researchers wish to quote publicly made comments in reports or to pass these on to people not bound by the ICC/ESOMAR Code (or a contract linked to this), they must first check if the user’s identity can be easily discoverable using online search services. If it can, they must make reasonable efforts to either seek permission from the user to quote them or mask the comment to such an extent that the identity of the user cannot be obtained.</i></p> <p><i>The degree of masking required will depend on the nature of the comment and its author. Masking can be applied in varying degrees</i></p>
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				<p>ranging from just changing the odd word through altering key features of a comment to précising. It is the responsibility of the researcher to decide which is most appropriate.”</p> <p>“Masking is unlikely to be sufficient in many B2B contexts or when researching very small groups, as identification is highly likely even if masked. When a researcher passes a masked comment on in a report to a client, they should clearly indicate if it has been masked.”</p> <p>Defining social media areas</p> <p>“There are three areas in which social, opinion and market research could be conducted. These are defined as follows:</p> <ol style="list-style-type: none"> 1. Public social media: This covers the majority of SM. It includes all places where access has been set by the website or the user to ‘public’ and entry is without any form of entry barrier. It can also include those where a username or password is required, but these are required for identification or site revenue reasons, rather than to protect the privacy of the data posted. Examples include public profile pages of SM networks; public micro-blogging posts; and many forums (including those where a username may be required, but is automatically granted, that is they are not moderated).” <p>The CASRO Guidelines states that:</p> <p>“A public space is one in which most participants have a reasonable expectation that anyone can read, cite, reproduce, link, collect and share their contributions, statements and media.”</p> <p>“In the case of SMR conducted in public spaces the researcher must have a reasonable basis to conclude that most users would be aware that the information they provide could be viewed by anyone with relative ease.”</p> <p>“When quoting comments from this area, masking may be required when negative consequences to the participant could reasonably arise from disclosure that results in the violation of the privacy of the participants.”</p> <ol style="list-style-type: none"> 2. Private social media: This covers areas where the user or the website do not want the data to be publically accessible. All require username identification for access, although this is not a
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				<p><i>blog or co-creational project.</i></p> <p><i>These terms must be simple, clearly worded and easy to understand. Members must be fully aware of:</i></p> <ul style="list-style-type: none"> - <i>The purpose of the space - that it is for research, but in the case of a MROC, that they may be exposed to marketing information for research purposes only. This might include incentives for panel participation noting that using the client's products could be regarded as marketing in some countries.</i> - <i>That all data may be shared with the client – this is especially important since some members will actively share real names and photos.</i> - <i>How it could be used</i> - <i>The rules for interacting (i.e. no cyber-bullying, defamatory comments etc)</i> - <i>The site privacy policy including requirements listed in the Online Research guideline.</i> <p><i>Unlike public internet areas, content can be copied and scraped and utilised for any research purpose, subject to members being fully aware of these applications. However the personal identity of those making comments must be protected.</i></p> <p><i>Where spaces are communal, members should be warned about contributing personally identifiable information. In addition on sign up, researchers should provide reassurance to community members that they will never ask for information that could create a risk of identity theft if lost, misused or disclosed to an unauthorised party.”</i></p> <p><i>“The role of moderators and clients should be unambiguously identified as such in all their interactions and communications with members. However care needs to be taken to protect them from being easily contacted outside the project, so it may be necessary to withhold full names and/or emails of such people and to utilise secure email systems within the relevant software.”</i></p>
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May 2011	3	2.1		<p>The Code provides pan-European guidelines, although its development has focused upon the major European markets of France, Germany, Italy, Spain and the UK, plus the USA and the Scandinavian territories of Denmark, Finland, Norway and Sweden.</p> <p>In Sweden, article 42 of 'Ethical Rules for the Pharmaceutical Industry in Sweden' requires members of LIF (the Swedish trade association for the research-based pharmaceutical industry) and FGL (the association representing the manufacturers of generic pharmaceuticals in Sweden) to enter into a central database details of market research studies to be conducted with healthcare professionals in Sweden. The LIF guidelines also apply for Skålland in Denmark</p> <p>So the commissioning company - if they are LIF members - must record the following information:</p> <ul style="list-style-type: none"> - Timeline - Commissioning pharmaceutical company (incl. contact person) - Market research agency (if appropriate) - Short description of the survey - Payment to participating doctors <p>This information must be logged no later than the day it was sent into the field. The database can be found at the following web address - http://www.lif.se/cs/default.asp?id=59886&ptid</p> <p>If a market research study is commissioned by a parent company without the knowledge of the Swedish affiliate the study does not have to be registered.</p> <p>When lists of named individuals are used for sample selection the source of the list must be revealed to potential respondent(s) at an appropriate point in the interview, if requested. In Finland, a researcher must not disclose the identity of the sponsor (unless legally required to do so) to any third party without the permission of the sponsor.</p>
	12	11.2		
	13	11.7		

	14	11.11		<p>In Germany, Italy Norway and Sweden, the ADM, ASSIRM, and LIF respectively, recommend that market research appointments with healthcare professionals (HCPs) should be made outside working hours and that those HCPs that are employees are not interviewed on their employer's premises. However the preferences of the HCPs can be taken into account. In Italy this refers to HCPs when employed by the national health service (SSN) only.</p> <p><i>Guideline on Interviewing Physicians for Market and Social Research Purposes www.adm-ev.de/richtlinien Aug 2009</i></p> <p><i>ASSIRM, Directive on the interviews with medical staff for purposes of market research and social</i></p> <p>In Norway drug brand or generic names cannot be used within market research unless approval for the study from the Norwegian health authorities has been given.</p>
	17	11.28		<p>In Sweden if remuneration for healthcare professionals exceeds SEK 1000, LIF guidelines state that the study will no longer be considered market research in which case healthcare professionals require the approval of their superior(s) to participate.</p>
	36	21.1		<p>When conducting research with children or young adults, a 'child' is a minor 15 years old or less and a 'young person' is 16 or 17 years of age. Although in Sweden, children are defined as 14 years or younger and in Germany, a child is minor 13 years old or less and a young person is 14 to 17 years of age.</p>
22 Feb 2011	6	4.2	NEW ADDITION	Market research is not a commercial communication or a selling opportunity.
22 Feb 2011	6	5.2	<p>In general non-research exercises have the following characteristics:</p> <ul style="list-style-type: none"> - Anonymity and confidentiality are not guaranteed - If the data are collected on an identifiable basis, direct action (such as selling or direct marketing) will or may be 	<p>In general non-research exercises have the following characteristics:</p> <ul style="list-style-type: none"> - Anonymity and confidentiality are not guaranteed - If the data are collected on an identifiable basis, direct action (such as selling or direct marketing) will or may be taken - The exercise aims primarily to encourage people in general or

			<p>taken</p> <ul style="list-style-type: none"> – The exercise aims primarily to encourage people in general or at random to express views, rather than to achieve robust data based on systematically targeting specific sectors of the population or on the whole range of views from a representative sample of the relevant population. <p>These definitions are based upon the UK's Market Research Society Code of Conduct. www.mrs.org.uk/standards/codeconduct.htm Aug 2009</p>	<p>at random to express views, rather than to achieve robust data based on systematically targeting specific sectors of the population or on the whole range of views from a representative sample of the relevant population.</p> <ul style="list-style-type: none"> – The exercise promotes the aims or ideals of a client or organization – The exercise promotes the products or services of a client or organization. <p>These definitions are based upon the UK's Market Research Society's Regulations for Using Research Techniques for Non-Research Purposes Nov 2010</p>
22 Feb 2011	7	6.1	NEW ADDITION	<p>An IP address might constitute personal data in combination with other identifiable data but there is no international consensus about the status of IP addresses. Consequently if national law/regulations classifies IP addresses as personal data and it is not possible to differentiate between those IP addresses which are linked to an individual and those that are not, all the information collected should be treated as if it were personal data. In Germany an IP address is considered by law to be personally identifiable information.</p>
22 Feb 2011	9	6.8	<p>The transfer of personal data to non-EU/ countries is forbidden unless there is adequate privacy protection in place. In order to ensure adequate privacy protection, the US Department of Commerce, in consultation with the European Commission developed the 'Safe Harbor Framework'. US based organisations can guarantee adequate data privacy protection through voluntary participation in the Safe Harbor Program. Organisations that decide to participate must comply with its requirements and publicly declare that they do so. www.export.gov/safeharbor/eg_main_018236.asp Aug 2009</p>	<p>The transfer of personal data to non-EU/ countries is forbidden unless there is adequate privacy protection and specific data protection contractual arrangements in place.</p> <p>There are various ways in which to comply with the EU Directive in non-EU countries depending upon the circumstances:</p> <p>Model Clauses – The European Commission has published model contractual clauses. These are designed to facilitate the safe transfer of personal data from the European Economic Area (EEA) to all third countries, protecting the privacy of individuals. The European Commission has produced two sets of model clauses. One covers controller-to-controller transfers and the other controller-to-processor transfers. The clauses commit all parties to complying with the data protection standards required by the Data Protection Directive.</p> <p>Binding Corporate Rules (BCR) – These are a mechanism for transferring personal data (outside the EEA) throughout a single multi-national organisation. BCR have to be approved by each European data protection authority involved but the approval process</p>

				<p>is simplified - an application is made to one national 'lead' data protection authority in Europe and that authority then liaises with the other authorities to seek approval.</p> <p>For further information on Model Clauses or Binding Corporate Rules see: http://www.ico.gov.uk/upload/documents/library/data_protection/detailed_specialist_guides/international_transfers_legal_guidance_v3.0_171208.pdf</p> <p>The Safe Harbor Framework – In order to ensure adequate privacy protection, the US Department of Commerce, in consultation with the European Commission developed the 'Safe Harbor Framework'. US based organisations can guarantee adequate data privacy protection through voluntary participation in the Safe Harbor Program. Organisations that decide to participate must comply with its requirements and publicly declare that they do so.</p> <p>Further information is available at: ec.europa.eu/justice_home/fsj/privacy/modelcontracts/index_en.htm www.export.gov/safeharbor/eg_main_018236.asp Aug 2009</p>
22 Feb 2011	9	6.9	NEW ADDITION	<p>It is good practice for researchers to keep copies of e-mails and other documents received from respondents agreeing to, or restricting, the use of or access to their personal information. This is a legal requirement in some countries, amongst others, all European Union member states and US companies that participate in the US-EU Safe Harbour Framework.</p>
22 Feb 2011	12	11.1	<p>In Spain, the Surveillance Unit of the Pharmaceutical General Assembly, the Farmaindustria Deontological Surveillance Unit (DSU), must approve all market research undertaken in Spain and majority funded by pharmaceutical members if the potential respondents (i.e. the interviewees) are known to the pharmaceutical company. This is NOT mandatory if:</p> <ul style="list-style-type: none"> – The pharmaceutical company funds less than 50% of the study OR – The study has already been reported to the healthcare authorities or approved by a certified Clinical Research Ethics Committee OR – The pharmaceutical company does not have access to the identity of participating healthcare professionals and has 	<p>In Spain, pharmaceutical companies must provide prior notification to the FARMAINDUSTRIA Code of Practice's Surveillance Unit (CPSU) when carrying out, financing or sponsoring market research studies. This is NOT mandatory if:</p> <ul style="list-style-type: none"> – The pharmaceutical company funds less than 50% of the study OR – The company does not have access before, during or after study, to the identity of the participating healthcare professionals and has not intervened in their selection beyond defining participating group described in the study protocol OR – The study does not provide direct or indirect remuneration to the participating healthcare professionals OR – The study involves paid participation of less than 20 healthcare professionals. It is not allowed to split a study into smaller units

			<p>not influenced their selection other than defining collective recruitment criteria OR</p> <ul style="list-style-type: none"> – The study does not provide any respondent remuneration (direct or indirect) <p>Pharmaceutical company and execution details are required and must be supplied to the DSU at least 10 days before the start date of the study.</p>	<p>that share approach, objectives and methods. Communication should be addressed to the Farmindustria Code of Practice Surveillance Unit (CPSU) and sent at least ten working days before the study is due to start.</p>
22 Feb 2011	12	11.2	NEW ADDITION	Clients must be informed if any part of the study is to be sub-contracted outside of the agency. If requested the identity of the sub-contractor must be provided.
22 Feb 2011	13	11.5	<p>DELETED - It should also be remembered that:</p> <ul style="list-style-type: none"> – Those included on a list must be told of the purpose of the list when giving consent for the inclusion of their personal data – The client company must not be informed of the identity of market research participants, i.e. who on the list was interviewed. 	<p>If the list contains information not in the public domain, those listed must give permission for their personal data to be held and told why their personal data is being held</p> <p>The client company must not be informed of the identity of market research participants, i.e. who on the list was interviewed.</p>
22 Feb 2011	13	11.6	<p>DELETED - If the respondent asks (during recruitment or interview) where their name was obtained, they must be told. The respondents' right to this information overrides the client's right to confidentiality. If there is concern that this information will bias responses it is reasonable to provide this information at the end of the interview, assuming the respondent agrees to this.</p>	When lists of named individuals are used for sample selection the source of the list must be revealed to potential respondent(s) at an appropriate point in the interview, if requested.
22 Feb 2011	13	11.8	NEW ADDITION	The type of organisation sponsoring the market research e.g. a pharmaceutical company
22 Feb 2011	14	11.9	NEW ADDITION	If the potential respondent/respondent requests the name of the sponsoring client it is not necessary to provide this information unless the sponsoring client company provided the list from which the potential respondent/respondent's name/contact details have been drawn.
22 Feb 2011	16	11.24	NEW ADDITION	Panel members should be made aware of the approximate level of commitment and/or length of time required before the incentive will be paid.
22 Feb 2011	16	11.25	NEW ADDITION	In Spain , payment of incentives must be in cash (cheques and bankers drafts are acceptable). Exceptionally, and with the prior authorisation of the USD some payments in kind may be made.
22 Feb 2011	16	11.26	NEW ADDITION	In the UK pharmaceutical companies must make publicly available details of payments made to healthcare professionals in relation to market research – <u>unless the company is <i>not aware</i> of the identities of</u>

				those participating in the market research. See ABPI Code of Practice for the Pharmaceutical Industry 2011, clause 20.2 – 20.3, for further details.
22 Feb 2011	18	13.3	When a topic is considered sensitive, respondents must be told explicitly the subject and content of the discussion. Sensitive topics include those that are judged to be sensitive to most people because of the nature of the subject or those that may be sensitive to a particular individual, because of that individual's past history.	When a topic is considered sensitive, respondents must be told explicitly the subject and content of the discussion. Sensitive topics include those that are judged to be sensitive to most people or a specific group of people because of the nature of the subject or those that may be sensitive to a particular individual, because of that individual's past history.
22 Feb 2011	20	13.25	Recorded data can only be given to clients if respondents have given their written consent for this. Respondents must be told: <ul style="list-style-type: none"> – To whom it will be given and shown – roles not names – For what purpose(s) it is likely to be used. Recorded data must not be used for any non-research purpose such as selling or training, without the explicit prior consent of the respondent. Researchers should ensure that recipients of recordings are aware of their obligations and agree to abide by these.	Recorded data can only be given to clients if respondents have given their written consent for this. Respondents must be told: <ul style="list-style-type: none"> – The name of the recipient company – To whom it will be given and shown – roles not names – For what purpose(s) it is likely to be used. Recorded data must not be used for any non-research purpose such as selling or training, without the explicit prior consent of the respondent. Researchers should ensure that recipients of recordings are aware of their obligations and agree to abide by these.
22 Feb 2011	20	13.28	The agency must ensure that the country or organisations in those countries to which any personal data are transferred have adequate data protection measures in place, particularly outside the EU. EphMRA recommends that US based organisations to which personal data is transferred from the EU are members of the Safe Harbor Program.	The agency must ensure that the country or organisations in those countries to which any personal data are transferred have adequate data protection measures in place, particularly outside the EU.
22 Feb 2011	21	13.33	NEW ADDITION	<u>Video and audio transmission of fieldwork</u> When using the services of a company to record, transmit and/or archive audio or video recordings, the commissioning company (whether market research agency or pharmaceutical company) must ensure that: <ul style="list-style-type: none"> – Respondent permission for this has been sought and granted in accordance with EphMRA's guidelines (13.19 to 13.32). It should be noted that providers of video/audio transmission services generally include a clause in their contracts that make it clear that it is the agency or client's responsibility to secure the appropriate consents and providers assume under the terms of their agreement that the required consents have been procured by the agency/client company before recording, transmission or storage takes place.

				<p>–To ensure that unauthorised viewers cannot access recorded material EphMRA recommends that the commissioning agency/client:</p> <ul style="list-style-type: none"> □ Ensures that comprehensive security measures are in place □ Access is password protected and restricted to authorised users (identified through a unique login id) and that login ids/passwords are distributed only by the project leader □ Authorised users agree in writing not to allow access to unauthorised personnel (see pro forma 4 – Client Agreement to Safeguard Confidentiality of Recordings). <p>Respondents are made aware that recordings may be archived for periods of time (1 year) that are longer than is required to fulfil purposes of the study. If the purposes of the study have been completely fulfilled i.e. the purposes of the study are redundant, respondents must give their explicit consent to prolonged storage – this is a data protection requirement.</p>
22 Feb 2011	24	13.42	NEW ADDITION	EphMRA strongly recommends that agencies consult the commissioning company’s adverse event reporting guidelines or the drug safety/pharmaco-vigilance department to ensure that internal adverse event procedures are understood and followed. Company adverse event reporting guidelines should not undermine or limit the requirements set out within EphMRA’s or national guidelines.
22 Feb 2011	25	14.8	NEW ADDITION	Adequate precautions must be taken to protect personal data, any sensitive data and confidential information against unauthorised access. This would include using the appropriate technologies to protect data stored on websites or servers and when data is transferred e.g. reliable encryption systems, firewall and user identification and password access.
22 Feb 2011	26	14.12	NEW ADDITION	In Spain , among other requirements, prescription medicines promotional materials must be based on scientific public relevant data and must be referenced. Market research studies not published in renowned scientific/medical publications (i.e. NEJM, Lancet, etc.), cannot be used under any circumstance as references for prescription medicines promotional materials.
22 Feb 2011	29	18.1		<p>Internet research currently refers to research in which a respondent – either on a single or successive occasions – is involved in any of the following:</p> <ul style="list-style-type: none"> – Completing research documentation online via the internet regardless of access route

				<ul style="list-style-type: none"> – Downloading research documentation from a server on the internet and returning it by email – Receiving research documentation incorporated into an email and returning it the same way – Participating in an online qualitative interview or discussion – Taking part in a measurement system which tracks web usage using specialist software installed on the user's computer. – Participating in an online message board – Collecting information from a social networking site – Any other collection of personal data in the online environment for the purpose of (market) research <p>www.mrs.org.uk/standards/internet.htm</p>
22 Feb 2011	30 31	18.12 & 18.20	<p>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.</p> <p>www.casro.org/codeofstandards.cfm#sectionI.B. 3 Aug 2009</p> <p>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.</p>	<p>Cookies store specific information about online browsing. EU legislation (passed late 2009 and to be enacted in to national legislation by April 2011), 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". So the use of cookies must be disclosed, as well as a clear description of the data collected and the uses to which it will be put – this must be easily accessible - and explicit consent may be required (depending upon national legislation - in the UK this is a legal requirement in accordance with the Privacy and Electronic Communications Regulations).</p> <p><u>Using identification and tracking technologies/software for market research purposes</u></p> <p>Respondents must always be told at the first opportunity when software is being used to collect information about them (sometimes referred to as spyware or, malware if used covertly), they must also be told:</p> <ul style="list-style-type: none"> – Why it/they are to be used – If the data subject's information is to be shared – That they can turn them off or remove them. <p>Explicit permission for downloading software to be used for market research purpose should be sought and a means provided to address questions.</p> <p>ESOMAR provides example disclosure statements within its Guidelines for Online Research 2010.</p>

				<p>In Germany websites that use analytics tools must give users the chance to opt out.</p> <p>Within its Guidelines for Online Research 2010 ESOMAR details a series of 17 'Unacceptable Practices' that researchers must forbid or prevent. EphMRA members are referred to this list for further information.</p> <p>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</p>
22 Feb 2011	31	18.19	NEW ADDITION	<p>Clients must be made aware of the potential risks of using confidential information in internet surveys (e.g. within product profiles). Agencies should be required to implement strict security procedures. Confidential information even if protected by non-disclosure agreements is easily /printed/stored/forwarded and practically impossible to remove from circulation.</p>
22 Feb 2011	32	18.21	Panel members must be made aware that they are members of a panel. Access panels are a sample database of potential respondents who declare that they are willing to receive invitations to participate in future internet interviews.	<p>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 internet interviews. At recruitment potential panel members must be told that their personal may be stored for further market research.</p>
22 Feb 2011	32	18.23 – 18.25	<p><u>Internet Forums</u></p> <p>Internet chat rooms that are open to anyone i.e. users are not required to join or register or apply for membership before being permitted to participate; provide information in terms of the views expressed and the identity attached that are in the public domain, this information may be used by researchers without seeking consent. However views expressed in online areas that are 'walled gardens' (do require membership of some sort) such as networking sites, should be treated as private, researchers should announce their presence and seek co-operation. Source: ESOMAR Guide on Passive Data Collection, Observation and Recording, Nov 2008)</p> <p>www.esomar.org/uploads/pdf/ESOMAR_Codes&Guideline-Conducting_research_using_Internet.pdf Aug 2009</p>	<p><u>Social Media</u></p> <p>Social media is defined by ESOMAR as "internet based platforms and technologies that permit users' interaction and/or facilitate the creation and exchange of user generated content."</p> <p>When conducting social media market research, researchers are bound by the terms and conditions attached to access of the online services. Many service providers include intellectual property rights clauses that prohibit copying of material without permission. Researchers should ensure that they abide by the terms and conditions attached to use of site content.</p> <p>ESOMAR has proposed the following classification of social media space:</p> <p>Public space - a place where content is contributed with the assumption that it could be read by anyone in the public and where contributors could not be surprised that it is linked to/copied/cited. Examples include many public blogs or comments left on news</p>

				<p>websites.</p> <p>Semi-public space - a place where people contribute content which although technically open to all to read, many would not expect it to be read or used by people not involved in the specific topic or conversation.</p> <p>The boundary between public and semi-public space is open to interpretation and researchers are encouraged to act with caution and regard sites as 'semi-public' if they have doubts. Examples include Facebook home pages and many niche (but open) forums/communities. It also includes all forms of open synchronous online activity e.g. open chatrooms, Twitter, etc.</p> <p>Private space - a place where most users would expect their comments to be private and which is available only to genuine community members. They are often called 'walled gardens' as they can only be accessed after the user has obtained a login and/or password, even if entry is automatic. Examples include many private forums, communities and chatrooms as well as instant messaging.</p> <p>Specific market research space - an online place specifically created for market, social and opinion research purposes where users have been informed of its function and the use to which their comments might be put. Typically (but not always) these are also private spaces. Examples include Market Research Online Communities (MROC's).</p> <p><i>ESOMAR Guideline on Social Media Research, Consultation Draft, Feb 2011</i></p> <p>The following guidelines apply within each type of 'space':</p> <p>Public space - may be used by researchers, although it may be necessary to 'cloak' comments if they could be in any way harmful to the individual (e.g. embarrassing). Cloaking means altering information so that it cannot be traced back to the contributor.</p> <p>Semi-public space – researchers should not pass on any identifiable information.</p> <p>Private space – market research can only take place with the consent of the service provider. Researchers should announce their presence and seek the co-operation of site participants. Researchers must gain the consent of participants to quote them and without this consent,</p>
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				<p>all comments should be cloaked. Researchers must not pose as an 'ordinary' participant e.g. on a patient website to gather information - their role and purpose must be transparent.</p> <p>Specific market research space – The same guidelines apply to these as to other forms of internet market research.</p> <p>Using Social Media Space for Market Research Purposes</p> <table border="1"> <thead> <tr> <th>Space</th> <th>Available for researchers</th> <th>Identifiable in reports</th> <th>Cloaking of verbatim quotes in reports</th> </tr> </thead> <tbody> <tr> <td>Public space</td> <td>Yes, subject to service Terms of Use</td> <td>Yes, except if might cause harm</td> <td>No, only required if it might cause harm</td> </tr> <tr> <td>Semi-public space</td> <td>Yes, subject to service Terms of Use</td> <td>No, except with user permission</td> <td>More likely to be required than a public space and essential if it might cause harm</td> </tr> <tr> <td>Private space</td> <td>Only with permission of service</td> <td>No, except with user permission</td> <td>Essential unless user gives permission to cite</td> </tr> <tr> <td>Market research space</td> <td>Yes</td> <td>Possible, subject to sign up agreement</td> <td>No, only required if it might cause harm</td> </tr> </tbody> </table> <p>Source: <i>ESOMAR Guideline on Social Media Research, Consultation Draft, Feb 2011</i></p>	Space	Available for researchers	Identifiable in reports	Cloaking of verbatim quotes in reports	Public space	Yes, subject to service Terms of Use	Yes, except if might cause harm	No, only required if it might cause harm	Semi-public space	Yes, subject to service Terms of Use	No, except with user permission	More likely to be required than a public space and essential if it might cause harm	Private space	Only with permission of service	No, except with user permission	Essential unless user gives permission to cite	Market research space	Yes	Possible, subject to sign up agreement	No, only required if it might cause harm
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22 Feb 2011	39	Glossary	NEW ADDITION	Carer/Caregiver – Professionals or unpaid relatives/friends who provide care for those who because of illness or disability require support, this care may be medical and non-medical.																				
22 Feb 2011	39	Glossary	NEW ADDITION	Data Controller - A person who alone, jointly or in common with others determines the purposes for which and the manner in which any personal data are processed and is responsible for ensuring that the provisions of Data Protection legislation are complied with.																				
22 Feb 2011	39	Glossary	NEW ADDITION	Data Processor - Any person (other than an employee of the Data Controller) who processes data on behalf of the Data Controller.																				
22 Feb 2011	39	Glossary	NEW ADDITION	Public Domain – Information, which is published and generally accessible or available to the public, content that is not owned or controlled by anyone, intellectual property being not protected under patent or copyright, in market research context it refers to																				

				information that is freely available, without restriction.
6 Sept 2010	7	6.1	NEW ADDITION	If a private company or organisation hold personal data it is covered by the Data Protection Directive if it either is held on a computer or is held on a 'relevant filing system'. A relevant filing system is one which is structured by reference to individuals, or by reference to criteria relating to those individuals, in a way which allows information relating to specific individuals to be readily accessible.
6 Sept 2010	11	11.4 & 11.5	<p>Passing on contact details (i.e. personal data) of potential respondents from which to draw a sample i.e. contact lists, is allowed; as long as individuals upon the list have given their consent to this when their details were added to the list.</p> <p>When studies are conducted that draw respondents from a list supplied by an agency, recruiter or the client company, the list provider must have notified the relevant authorities in line with local data protection requirements e.g. the CNIL in France.</p>	<p>When studies are conducted that draw respondents from a list supplied by an agency, recruiter or the client company, the list provider must ensure that the list conforms to local data protection and privacy legislation.</p> <p>Lists that are drawn from sources within the public domain do not generally require the permission of the individuals listed to have their personal details held (<u>all</u> of the data must be drawn from the public domain). So if for instance a list of healthcare professionals (HCPs) was drawn up from health centre websites that listed the HCPs working there, this would not require the HCPs prior consent, and if these details are passed to another party and that party is contractually designated the 'data processor' (the list holder being the data controller), then again, the permission of the individual need not be sought. Similarly if a list of detailed physicians was passed to a market research agency to allow them to draw a sample from it, as long as the agency had been contractually designated the data processor (the client company being the data controller) this does not constitute the 'transfer' of personal data and does not require the permission of the listed individuals.</p> <p>If however local law/regulations demand that the explicit permission of those on the list is required before their personal details are passed on as in Italy, this must be complied with. In Italy, data that is used that is not publicly available should be 'certifiable' – those that hold the data must have the consent of the individual and evidence of how they obtained the data. It is also strongly recommended by EphMRA that the responsibilities of list suppliers are made explicit and agreed to in writing within some form of project agreement, such as the contract.</p> <p>It should also be remembered that:</p>

				<ul style="list-style-type: none"> – Those included on a list must be told of the purpose of the list when giving consent for the inclusion of their personal data – The client company must not be informed of the identity of market research participants, i.e. who on the list was interviewed.
6 Sept 2010	13	11.11	The use of client databases as a basis for drawing a sample is allowed as long as the individuals listed have consented to their personal details being held upon the list.	The use of client databases as a basis for drawing a sample is allowed as long as local regulations have been adhered to as detailed in 11.4.
6 Sept 2010	15	11.25	In the USA some states have introduced legislation that requires the reporting of or bans the giving by pharmaceutical companies of ‘gifts’ to medical professionals, valued above a specific dollar value (usually \$25 to \$50). While the intent of the proposed legislation is to eliminate or expose undue influence practices of pharmaceutical companies on physicians, in some cases ambiguities in the legislative language can be interpreted to implicate market research payments to physician respondents. The Massachusetts law and the proposed Federal legislation have been clarified to confirm that market research payments to physicians are not intended to be subject to restriction or disclosure, if the pharmaceutical client is not identified to the physicians and the physician is not identified to the client. At this writing (November 2009) only Vermont requires reporting of pharmaceutical market research payments to physicians and only Minnesota prohibits payments totalling \$50 or more annually from a pharmaceutical company to a physician for participation in market research.	In the USA the federal Sunshine Act signed into law in late March does not (as feared) include mandatory reporting of survey incentives made by drugs companies or their agents to doctors. The Bill excludes thank you payments for taking part in surveys provided the company sponsoring the research is unaware of the respondents’ identity. The position of the states of California, Columbia, Maine, Massachusetts, Minnesota, Vermont and West Virginia is detailed within the appendices on page 38 - US State Law Summaries.
6 Sept 2010	21	13.34	NEW ADDITION	Where companies have their own adverse event reporting procedures, these should be adhered to.
6 Sept 2010	25	16.3	Researchers must take special care when contacting respondents via mobile phones (whether by voice, text or email), with regard to respondent safety and unnecessary intrusion. It is recommended that interviews by mobile/WAP phone are preceded with a question such as " <i>is it convenient to proceed with this interview now?</i> " The respondent must be told the likely length of the interview. It may be more convenient to arrange an appointment to call back at a different time or via a land line.	Researchers must take special care when contacting respondents via mobile phones (whether by voice, text or email), with regard to respondent safety and privacy . It is recommended that interviews by mobile/WAP phone are preceded with a question such as " <i>is it convenient to proceed with this interview now?</i> " The respondent must be told the likely length of the interview. It may be more convenient to arrange an appointment to call back at a different time or via a land line. Researchers should try to establish as early as possible if the number to be contacted / contacted is that of a mobile or a fixed-line telephone.

6 Sept 2010	26	16.6	NEW ADDITION	If using a mobile phone to respond to a market research survey means the respondent incurs a cost this should be reimbursed, researchers must ensure that participating in a market research study does not disadvantage respondents financially.
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.
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.
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)

New Appendices

California

The law requires pharmaceutical companies that do business in California adopt comprehensive compliance programs that is in accordance with the “Compliance Program Guidance for Pharmaceutical Manufacturers” which was developed by the U.S. Department of Health and Human services Office of Inspector General (OIG). The compliance program shall include policies for compliance with the Pharmaceutical Research and Manufacturers of America’s (PhRMA) “Code on Interaction with Healthcare Professionals”.

The law requires each pharmaceutical company to establish in its compliance program a specific annual dollar limit on gifts, promotional materials, or items or activities that the pharmaceutical company may give or otherwise provide to an individual medical or health care professional in accordance with the “Compliance Program Guidance for Pharmaceutical Manufacturers” and with the “Code on Interactions with Health Care Professionals”.

Excluded from the limits are

- Drug samples given to physicians and health care professionals intended for free distribution to patients, financial support for continuing medical education forums, and financial support for health educational scholarships if such support is provided in a manner that conforms to the OIG compliance program and the PhRMA code.
- Payments made to legitimate professional services provided by a health care or medical professional, including, but not limited to, consulting, are exempt from any limits, provided the payment does not exceed the fair market value of the services rendered and the payments are provided in a manner that conforms to the OIG compliance program and the PhRMA code.

District of Columbia

The law requires manufacturers and labelers to disclose and file annual reports of all prescription drug marketing costs, with some exceptions. The report shall specify the value, nature, purpose and receipt of expenses for:

- all advertising, marketing and direct promotion;
- with respect to all persons or entities licensed to provide health care in the state, the report shall specify the cost of:
 - education or information programs;
 - food, entertainment, gifts valued at more than \$25;
 - trips and travel; and
 - product samples, except for free patient samples.

Excluded from the reporting requirements are:

- marketing expense of \$25 or less per day per health care provider or entity;
- reasonable compensation and reimbursement for expense in connection with a bona fide clinical trial for a new vaccine, therapy, treatment, or indication;

- scholarships and reimbursement of expenses for attending a significant education, scientific or policy-making conference or seminar of a national, regional, or specialty medical or other professional association if the recipient is chosen by the association sponsoring the conference or seminar; and
- expenses associated with advertising an promotional activities purchased for a regional or national market that includes advertising in the District if the portion of the costs pertaining to or directed at the District or cannot be reasonable allocated, distinguished, determined or otherwise separated out.

Maine

In 2003 Maine passed LD 254/H 209 that requires manufacturers or labelers of prescription drugs to file annual reports with the department of Human Services which shall specify the "value, nature, purpose, and recipient expenditures" for:

- A. All advertising expenses;
- B. With regard to all persons and entities licensed to provide health care in the State, the cost of:
 1. educational or informational programs;
 2. food, entertainment, gifts valued at more than \$25;
 3. trips and travel; and
 4. product samples, except for free patient samples;
- C. The aggregate cost of all employees or contractors of the manufacturer or labeler who directly or indirectly engage in the advertising or promotional activities listed above, including all forms of payment to those employees within the state
Exemptions: expenses of \$25 or less; compensation and reimbursement of expenses for bona fide clinical trial activities; and scholarships and expenses for attending educational or policy conferences if the attendee was chosen by the sponsoring organization.

In 2005 Maine passed three laws addressing pharmaceutical marketing and direct-to-consumer advertising:

LR 487/LD 1618: prohibits pharmaceutical companies from advertising on television, radio or in print unless the material meets federal guidelines; includes clinical trial requirements that manufacturers "shall post on the public website of the federal National Institutes of Health or another publicly accessible website information concerning any clinical trial that the manufacturer conducted or sponsored beginning October 15, 2002; and includes a fee for prescription drug manufacturers that advertise in the state for maintaining the clinical trial database.

LR 1703/LD 1539: limits the pricing information that a pharmaceutical manufacturer must report to the state the average manufacturer price (AMP) and the best price as defined by federal law; eliminates the instructions on calculating other pharmaceutical pricing information and the requirement to describe the methodology for calculating pricing information that is reported; and strengthens the confidentiality protections afforded to the reported information.

LR 1703/LD 1541: delays implementation of the deadline for filing reports regarding marketing activities by pharmaceutical manufacturers; and clarifies that the Department of Health and Human Services may disclose that information to an entity that provides services to the department under the laws requiring those reports, but specifies that such disclosure does not change the confidential status of the information.

Massachusetts

In 2009 Massachusetts approved regulations which established a code of conduct for pharmaceutical and medical device manufacturers (“Code of Conduct”). The Code of Conduct was implemented for the purpose of preventing undue influence by pharmaceutical and medical device manufacturers on health care practitioners. The regulations require pharmaceutical and medical device manufacturers to (a) implement certain policies with respect to non-patient identified prescriber data, (b) adopt a code of conduct which prohibits certain activities and (c) disclose certain financial interactions between the company and covered recipients.

Code of Conduct

The Code of Conduct prohibits:

- Payments for entertainment or recreational items of any value;
- Payments of any kind including cash or cash equivalent made directly or indirectly, except as compensation for bona fide services;
- Giving, directly or indirectly, of any tangible items regardless of value (including token items such as pens, coffee mugs, gift cards, etc.) except as compensation for bona fide services;
- Any grants, scholarships, subsidies, consulting contracts, or educational or practice related items in exchange for prescribing, disbursing, or using prescription drugs, biologics or medical devices;

Meals are restricted and in some instances prohibited. Generally, meals provided to health care providers must be modest and occasional in nature and can not occur outside the practitioner’s office or hospital setting. The Code of Conduct prohibits meals that:

- Are part of an entertainment or recreational event;
- Are offered without an information presentation made by the company;
- Are provided to a healthcare practitioner’s spouse or other guest.

The Code of Conduct prohibits the payment, either directly or indirectly, for expenses associated with any CME event, third-party scientific event or educational conferences or professional meetings. Such expenses include

- Travel, lodging, meals, or other personal expenses;
- Compensation for time spent at the event;
- Sponsorship or payment for CME events that do not meet the Standards for Commercial Support as established by the Accreditation Council for Continuing Medical Education (ACCME) or its equivalent.

Permissible payments include:

- Compensation or reimbursement made to a health care practitioner serving as a speaker or providing actual and substantive services as a faculty organizer or academic program consultant for a CME or similar event, provided the payment:
 - Is reasonable;
 - Is based on fair market value; and
 - Complies with the standards for commercial support as established by the relevant accreditation entity.
- Sponsorship or payment for third-party scientific or educational conference, or professional meetings which are made directly to the conference organizers.

Financial Disclosure

Beginning July 1, 2010, and annually on or before July 1 of each year thereafter, every pharmaceutical and medical device manufacturing company must disclose the value, nature, purpose and recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50, which the company provides, directly or through its agents, to any person authorized to prescribe, dispense or purchase prescription drugs, biologics or medical devices in the commonwealth in connection with the company's sales and marketing activities.

For purposes of computing the \$50 threshold, fees, payments, subsidies and other economic benefits relating to separate events or transactions shall be calculated on an individual transactional basis and shall not be aggregated. Pharmaceutical or medical device manufacturing companies shall not structure fees, payments, subsidies or other economic benefits to health care practitioners to circumvent the reporting requirements.

All information provided under this disclosure requirement will be posted on a searchable, publicly available website.

Minnesota

In 1993 Minnesota passed a law which prohibits manufacturers or wholesale drug distributor, and their agents from giving any gift of value to a practitioner. A "gift" does not include:

1. professional samples of a drug provided to a prescriber for free distribution to patients;
2. items with a total combined retail value, in any calendar year, of not more than \$50;
3. a payment to the sponsor of a medical conference, professional meeting, or other educational program, provided the payment is not made directly to a practitioner and is used solely for bona fide educational purposes;
4. reasonable honoraria and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting;
5. compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project;
6. publications and educational materials; or
7. salaries or other benefits paid to employees.

Vermont

In 2009 Vermont passed a more restrictive pharmaceutical marketing law, banning gifts to physicians from industry. The law makes it unlawful for any manufacturer of a prescribed product or any wholesale distributor of medical devices, or any agent thereof, to offer or give any gift to a healthcare provider.

"Gifts" are defined as:

- Anything of value provided for free;
- Any payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care professional, unless:
 - It is an allowable expense as defined by the statute
 - The healthcare provider reimburses the cost at fair market value

“Allowable Expenditures” include:

- Payment to the sponsor of a significant educational, medical, scientific, or policy-making conference or seminar, provided:
 - (i) the payment is not made directly to a health care provider;
 - (ii) funding is used solely for bona fide educational purposes; and
 - (iii) all program content is objective, free from industry control, and does not promote specific products.
- Honoraria and payment of the expenses of a health care professional who serves on the faculty at a bona fide significant educational, medical, scientific, or policy-making conference or seminar, provided:
 - (i) there is an explicit contract with specific deliverables which are restricted to medical issues, not marketing activities; and
 - (ii) the content of the presentation, including slides and written materials, is determined by the health care professional.
- For a bona fide clinical trial.
- For a research project that constitutes a systematic investigation, is designed to develop or contribute to general knowledge, and reasonably can be considered to be of significant interest or value to scientists or health care professionals working in the particular field of inquiry.
- Payment or reimbursement for the reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual health care professionals on the use of a medical device if the commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the health care provider and the manufacturer.
- Royalties and licensing fees paid to health care providers in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the health care provider holds an ownership right.
- Other reasonable fees, payments, subsidies, or other economic benefits provided by a manufacturer of prescribed products at fair market value.

West Virginia

In 2004 West Virginia enacted a law requiring the reporting of pharmaceutical advertising costs. The law requires advertising costs for prescription drugs, based on aggregated national data, be reported to the state by all manufacturers and labelers of prescription drugs dispensed in the state that employs, directs or utilizes marketing representatives. The following are exempt from the disclosure requirements:

- All free samples of prescription drugs intended to be distributed to patients;
- All payments of reasonable compensation and reimbursement of expenses in connection with a bona fide clinical trial; or
- All scholarship or other support for medical students, residents and fellows to attend significant educational, scientific or policy-making conference of national, regional or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.