Ethics Committee Telecon	
Date:	**30 January 2014**
Event:	**Ethics Committee Telecon**
Time:	14.00 - 15.00
Place:	Teleconference
Participants:	Bob Douglas (BD)
	Bernadette Rogers (BR)
	Catherine Ayland (CA)
	Christine Mai (CM)
	Georgina Butcher (GB)
	Karen Giorgi Vigo (KGV)
	Piergiorgio Rossi (PR)
	Roni DasGupta (RDG)
	Solvea Lamarina (SL)
Distribution List:	Participants
Apologies:	Peter Eichhorn (PE), Robert Siegmund (RS)
Minutes by:	Bernadette Rogers (BR)

ACTION POINTS			
No.	**Action**	**Timeline**	**Responsibility**
#1.1	RDG to email CA regarding CNOM and the implementation of Loi Bertrand query	Now	CA
#1.2	Obtain an update on the drafted statement regarding Germany	Now	BR
	Contact the ABPI regarding EFPIA Disclosure Code	Now	CA
#1.3	CphMRA to be contacted again via an alternative route, Yong Huey Ling	February	BR
	Contact Rob Pollard in Beijing	February	BD
	Send Extensions information letter to Monica at IPSOS	February	BD
#2.1	Forward detail upon the characteristics of/differences between MR and NIS	February	KGV
#2.2	Contact KGV, CM and SL to arrange kick-off call	February	BR
#6.1	Develop a specific communication and PR message regarding competency testing	February	BR
#9.	A successor needs to be appointed to the Ethics Committee Chair	February	BR

[The number above relates to the items below]

Minutes		
No.	**Topic**	**Comment**
#1	**Code of Conduct**	**1.1 Annual Update.** Feedback was given by 5 Committee members but awaiting comment from PE regarding Germany. The consensus was to not include Argentina, so Brazil and The Netherlands will be part of this update, and Argentina will be reviewed again later during 2014, or for the 2015 update.

		Time wise the update is on target and should be through next week ready for publication on the online system. **1.2 Ongoing Issues** **France, Loi Bertrand.** EphMRA has issued a second update giving more concrete detail about the implications of Loi Bertrand. To further support members, EphMRA are going to take questions received so far, and produce a Q&A. EphMRA have also been in touch with ASOCS to request access for EphMRA members to key documents. There was a query about CNOM and the implementation of Loi Bertrand and this will be looked into separately. **Germany** – There had been nothing further received regarding employer permission. There is a legal requirement within the German Pharmaceutical Manufacturers Association Guidelines, and we are unaware of anything that PE may have found out since the last meeting. It was commented that the German doctor/employer issue is morphing more into an Ethics approval process, and that arguably this is an issue that is coming under the transparency umbrella. It was further commented that a statement has been drafted by ADM, ASI, BFM and DGOF and Germany members of the EphMRA Board have been asked to review it. It was thought they were going to pass this statement over to the FSA for them to consider. This is on the agenda for the next German local chapter meeting. BR to follow up on progress. **EFPIA Disclosure Code -** There has been no update from EFPIA. It was suggested that EphMRA contact the ABPI to see if they know what is happening regarding this and BR will email EFPIA again. **1.3 Extensions Update**. - **Turkey** – IPSOS replied to a follow-up email sent during the meeting with a contact, Anem to support the Code inclusion of Turkey. - **China** – an email was sent on 17th January by Thomas to David Wang, the head of CphMRA asking for an update. On attending a CphMRA meeting last year, there was a view that they wanted to develop their own code, although interested in some international alignment. They will be contacted again after the Chinese New Year. An alternative route to try is via Huey Ling, to see if she has any committee contacts. BD will also try to contact Rob Pollard in Beijing. - **India** – BD has spoken with Monica from IPSOS who is happy to be involved. Her boss is active in the Indian EFIMA equivalent. There is a standard outline letter that can be sent to Monica so she has more information on what is required. CA to forward to BD.
#2	**Adverse Event Reporting Guidelines & Training**	**2.1 Collecting evidence on AER update**. This is a Forward Thinking Group project. A summary has been issued to BD from that Group. **2.2 Adverse Event Training Update.** A small working group taskforce will be set up, to define parameters regarding the objectives for the training. There is already someone who has agreed to join. KGV, CM and SL also agreed to be part of this. **2.3 EMA Liaison** There has been a response from the EMA regarding the criteria for inclusion of multiple patients in AER, and whether EphMRA needed to go as far as the UK, that any patient group should be included. They advised that only if the doctor could number the group that AER be sent in, and they would

		consider this and come back to EphMRA. They replied in December, in that there is no more news, so the EphMRA guidelines stay as they are for 2014. They did however say that work is ongoing regarding the simplification of reporting requirements.
#3	**Code of Conduct Code Mark**	**3.1** Following the decision that the practicalities of implementing this would be too difficult, The Board has asked the Group to reconsider with a view to introducing a Code Mark. Therefore, the proposal following discussions between BD, CA and BR is to conduct a small-scale consultation. Firstly, take advantage of the compliance network; a small group of action orientated, highly experienced market researchers in charge of compliance on the agency side, and to talk to them about our questions and issues and ask them to think through the practicalities of the Code Mark on our behalf. Then secondly, talk practicalities with a small group of chosen people from both the agency and client side. It was agreed this was a very practical approach. The aim is to go back to The Board for the AGM with a clear recommendation. Therefore, a deadline should be set for the consultation so there is sufficient time to discuss and agree what the recommendation is, so that it is ready for the AGM.
#4	**REC Approval**	**4.1** The Board has asked us to look at this, following concern that there are increasing requests for ethics approval for Market Research. It is possible to make the requirements more explicit in the Code and write a discussion paper on the issue for members to be used as a reference document. It was suggested that supporting documentation in a Q&A format with references be made available to demonstrate when needed, some of this work has already been done. Again, the compliance network could be brought in to look at this. It was asked that if anyone has something to share to add to the sources and information, then please do so.
#5	**Disclosure Code EFPIA**	**5.1**
#6	**Competency Test Training**	**6.1** The number of competency tests done over the years and how many individuals and agencies had been through the test was presented. The agency figures were low, and people and agencies need to be encouraged to take this more seriously. Feedback from the IMM meeting made it clear that members had not appreciated how low the numbers were and that communication and PR needed to be developed and the right message given in a specific campaign. **6.2 Combined EphMRA/BHBIA Test.** This is in the final phase of testing and is being tweaked by BHBIA regarding their terminology, awaiting feedback from a question from CA. Once the final tweaking is done, it will be ready.
#7	**IMM Meeting**	**7.1**
#8	**Ethics Webinars**	**8.1** There are two webinars due in March and April. 20 March – Code of Conduct for Non-Market Researchers 3 April – Joint ESOMAR webinar
#9	**AOB**	**9.1** After 5 years, BD has decided to step-down as Ethics Committee Chair to focus on other things he wants to do. He was thanked by the EC for his hard work. If there is someone interested in taking up this role, contact BR.

COMMITTEE MEMBERS ARE ASKED TO RESPECT THE CONFIDENTIALITY OF THE INFORMATION THAT IS EXCHANGED DURING COMMITTEE DISCUSSIONS – THANK YOU.