EphMRA Committee Meeting Actions		
Date:	23 June 2015	
Event:	**Ethics Committee Meeting**	
Time:	11.30am - 2pm	
Place:	Amsterdam, Beurs.	
Participants:	BB	Bettina Brust
	CA	Catherine Ayland
	GB	Georgina Butcher – Co-Chair
	IB	Ian Barker – Co-Chair
	KJ	Katie Joyner
	PR	Piergiorgio Rossi
	RDG	Roni DasGupta
	XR	Xander Raijmakers
Apologies:	BR	Bernadette Rogers
	CM	Christine Mai

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

ACTIONS			
No	**Item/Issue**	**By**	**Date**
2.2	**Key Points Booklets**		

	▪ Additional Booklets to be produced:
	  – Practical Guide to Data Protection (for international healthcare MR)
	  – Transparency/Disclosure
		BR/CA	TBC

	▪ Inter-country differences to be updated	BR/CA	TBC
	▪ Build PR for the Booklets into ethics communications.	BR	
3	**Ethics Environment and Updates**		
	▪ Immediate updates on Russia and France will be issued.	CA	Jul/Aug
	▪ An update on the outcome of the data protection trilogue talks will be issued when this information is available.	CA	TBC
	▪ The need to refresh consent and anticipate multiple non-MR uses of MR data for which to secure consent, will be incorporated in the 2016 Code update.	CA	Oct
5	**Public Affairs**		
	▪ Arrange to do a presentation to EFPIA to explain and promote the value of MR, EphMRA and our Code at a suitable EFPIA meeting	BR	
	▪ Whilst approaching the FSA with a practical suggestion for how to go about securing employer permission for market research was discussed (the EC to develop the solution BB and XR to support from the agency and company perspectives) BR has suggested that the most appropriate route is through the panel (FSA/BVM/ADM) that are already considering this issue (and advised at the last Germany Chapter meeting) and that we also include Alexander Rummel who has been involved as convenor of the chapter meetings, this will ensure a consistent approach.	BR/CA/ BB/XR	Jul/Aug
	▪ Offer CASRO and PMRG EphMRA updates to share with their members	BR	
	▪ Try to get direct references to the EphMRA Code on to CASRO and the PMRG's websites	BR	July
	Training – Future Plans		
	▪ A list of possible topics will be circulated by email to EC members who will be asked to rate the different topics on how useful they would be for members	CA	
	▪ Consider inviting CASRO and PMRG members to join the 'Country Differences' webinar scheduled to take place in October, free of charge. This would be a one-off invite to help develop relationships.	BR	
	PR & Communications ▪ Examine the practicality of developing a target list for ethics emails made up of compliance contacts	BR	
	Any Other Business – Training and Test Access ▪ Examine whether a means by which immediate access to training and tests could be made available (without having to wait for a code/key).	BR	

	Date of next meeting Date of next meeting to be scheduled after 28 September 2015	CA/BR	

MINUTES			
No	**Item/Issue**		
1	**New members** Bettina Brust and Katie Joyner were welcomed to the Ethics Committee. We will have another new member joining us at our next meeting – Mattias Blomgren, Head of Market research, Business Intelligence, Europe & East Africa, Janssen Cilag.		
2.1 **2.2**	**Key Points Booklets** Eight booklets are currently available on the website providing a brief summary of key elements/issues within the Code of Conduct. The original series planned has now been completed. Feedback from the Ethics Committee, although rather limited was positive, they provide useful, digestible information particularly for those new to MR. Some agency members of the EC pass them on to clients. Feedback from the Compliance Network (CN) is that these are useful supporting documents when discussing issues with clients. The CN suggestion that an additional Key Points booklet outlining 'key considerations for client company (FM) market researchers' was discussed. When consideration was given to the example issues raised, there were several focusing on data protection and so it was concluded that another Booklet should be produced 'Practical Guide to Data Protection' (for international healthcare market research. The following are examples of issues for inclusion (previously highlighted by a CN member): • Insisting that HCPs must agree to provide their contact names if an AE is raised. Respondents who do not agree must be screened out. However, legal insist that we cannot provide the name of the pharma client at the screener stage as this will be promotion. • Insisting that we provide recordings of the interviews so they can conduct source data verification on the interviews for AEs, regardless of the respondent's wishes. It was also suggested and agreed that a second additional booklet on Transparency/Disclosure should be developed too. It was suggested that a third booklet on inter-country differences was produced but the EC was reminded that such a document exists although not in booklet form but it needs updating. It was suggested and agreed that it should be updated and reviewed by both the EC and the CN before release. There was discussion about awareness and promotion of the Booklets too. It was considered necessary to promote awareness of the booklets (and through this EphMRA and the Code) as much as possible and not just to members but to other organisations such as the PMRG, the CASRO and the MRA in the USA – although the booklets would only be available to EphMRA members. RDG has strong contacts		

	within these organisations and offered her support in this area. It was agreed that it important to build PR for the Booklets into our communications.
3	**Changes to the Ethics Environment** Each Committee Member provided a brief update highlighting key (ethics) issues and likely 2015-2016 developments: **Germany** – Bettina Key concerns: - Employer permission and the need for a practical approach - The Code consent templates are unsuitable in Germany - The absence of training materials and tests in the local language – it was explained that this issue has been discussed extensively in the past and the EC has decided not to make materials available in local languages. **France** – Christine, delivered by Ian – notes attached **UK** – Georgina Ongoing issue is the introduction of the disclosure requirements. Concern about the ongoing case about the use/adequacy of the Safe Harbor agreement was raised too. **Russia** – Ian The Russian Data Localisation law 2014 to be effective from 1 September 2015 requires that the personal data of Russian citizens must be held in Russia and this must be the case even if there is no local presence of the company that collected the data in Russia. **Italy** – Piergiorgio Assirm is actively lobbying with regard to law 165, Employer Permission. There seems to be mixed adherence to it. There is an opportunity not to have to adhere if doctors are employed less than 50% by in public healthcare. Whether MR could be classified under publishing (to which law 165 does not apply) is also being explored as is whether an annual permission could be given. **USA** – Roni The Sunshine Act requirements still causes concern and leads to regular questions. **Netherlands** – Xander An updated Code of Conduct is to be released by the MOA. **Impact of new technologies** – Katie Two key issues are emerging – the need to 'refresh' consent and the frequency this is required and secondly consent for multiple purposes, with the increasing availability of new technologies to capture and store data it opens up the data to new uses however generally speaking personal data can only be used and stored for those purposes that consent has been given and so potential non-MR uses need to be anticipated and consent for these sought.

	Data Protection in Europe – Catherine – notes attached Follow-up discussion was held to establish what, if any, are the implications for EphMRA ethics initiatives in 2015/16. The following actions were agreed: - Immediate updates on Russia and France will be issued. - An update on the outcome of the data protection trilogue talks will be issued when this information is available. - The need to refresh consent and anticipate multiple non-MR uses of MR data for which to secure consent, will be incorporated in the 2016 Code update.
4	**Balance between International and National Issues** The EC were asked to consider whether the balance of the time EphMRA spends monitoring and researching single-country national issues vs international issues is proportionate and appropriate to members' needs and the resources available. The questions was asked – should this be left to local/national associations and EphMRA adopt a more ESOMAR-like approach? It was unanimously and firmly concluded that EphMRA should continue to focus on national and international issues and dedicate the necessary resource to this. This is considered very important and very valuable, critical even. It was suggested that if necessary additional budget from the Board for this should be requested to make sure national issues can be pursued. It was also suggested that full use be made of the knowledge of members of the EC and CN to supplement and even save on central resource.
5	**Public Affairs** The EC were asked to consider how to take 'Public Affairs' forward. The following suggestions were discussed and agreed: International: EC would like to arrange to do a presentation to EFPIA to explain and promote the value of MR, EphMRA and our Code at a suitable EFPIA meeting National: Germany – ADM & FSA – Develop a practical suggestion for how to go about securing employer permission for market research, EC to develop the solution BB and XR to input from the agency and company perspectives BB offered to act as a go-between for EphMRA and the ADM when questions arise, as she has an existing relationship with Erich Weigand USA – CASRO & PMRG It was suggested that EphMRA offers CASRO and PMRG EphMRA updates to share with their members and hope that they will then reciprocate It was also suggested that we try to get direct references to the EphMRA Code on to CASRO and the PMRG's websites. RDG has offered to help with these initiatives.
6	**Training – Future Plans** It is anticipated that there will be 2 ethics webinars in 2016. It was agreed that a list of possible topics would be circulated by email to EC members who would be asked to rate the different topics on how useful they would be for members.

	Current suggestions include: - Compliance for those in the field - Compliance – in general - National issues – Loi Bertrand France, German Law, Safe Harbor USA - Basic introduction to the Code (for beginners) - Big data e.g. issues of ownership, access, consent - Update on 2016 Code It was also suggested that CASRO and PMRG members should be invited to join the 'Country Differences' webinar scheduled to take place in October, free of charge in order to encourage their members to rely on the EphMRA Code. Co-sponsoring of webinars e.g. with ESOMAR, EFPIA and other key organisations was briefly discussed, opportunities to do this would be welcomed.
7	**PR & Communications – Progress & Plan** A copy of the 2014/15 EC Comms Plan was attached to the agenda and the EC was asked for any suggestions for other PR/Comms initiatives that could help to promote ethics. There were no specific suggestions but there was a recognition of the need to increase awareness of EphMRA's ethics initiatives within member companies. It was suggested that EphMRA look at the practicality of developing a target list for ethics emails made up of compliance contacts.
8	**Any other business** Difficulties and delays accessing the training and competency tests was raised and it was generally agreed that this is a common problem. The EC asked if a means by which immediate access to the tests could be made available (without having to wait for a code/key). EC member feedback on a requirement to report AEs with no identifiable patient or patients was raised by IB but no other EC member had come across this requirement.
	Date of next teleconference 1 October 2015, 1-2pm (UK time)