Phase I Advisory Group
Minutes
10 February 2015
11:00 - 14:00

Present

Richard Tiner	Chair	RT
Catherine Blewett	Health Research Authority	CBl
Joan Kirkbride	Health Research Authority	JK
Clive Collett	Health Research Authority	CC
Charlotte Allen	Health Research Authority	ChA
Janet Wisely (Items 1 - 4)	Health Research Authority	JW
Jonathan Montgomery (Items 1-4)	Health Research Authority	JM
Deidre McCollam	Biokinetic	DM
Gary Johnstone	BioKinetic	GJ
Malcolm Boyce	HMR	MB
Kath Osborne	GM Central (REC Manager)	KO
Simon Lee	Quotient Clinical	SL
Rachel Bacon	Quotient Clinical	RB
Susan Tonks	Berkshire REC	ST
Christiane Abouzeid (by Phone 11:00-12:00)	BIA	CA
Keith Berelowitz	Richmond Pharmacology	KB
Ulrike Lorch	Richmond Pharmacology	UL
Ashley Totenhofer	Bloomsbury REC (REC Manager)	AT
Noel Landsman	Quintiles	NL
Anita Chhabra	Cambridge Central	AC
Peter Dewland	AHPPI	PD
Stephanie Ellis	Hampstead REC	SE
Jennifer Martin	MHRA	JMa
Adrian Baillie	Surrey Borders REC	AB
Alan Reuben	Westminster REC	AR
Roger Rawbone	GM Central REC	RR
David Carpenter	Berkshire REC	DC
Catherine Hack	REC A NI	CH
Jan Downer	Harrow REC	JD
John Keen	Oxford A REC & London City and East REC	JKe
Art Tucker	CCRA	AT

Item	Item details
1.	**Apologies** John Sheridan - Berkshire B REC Ian Skidmore - Hatfield REC Raj Bains - Oxford A REC
2.	**Minutes of previous meeting on:** 17 July 2014

	RT welcomed Jonathan Montgomery, Chair of the HRA Board and Janet Wisely, HRA Chief Executive, to the meeting and introduced them to the group, before welcoming those present to the meeting. The minutes of the meeting were agreed as an accurate record, subject to the following corrections. Page 7 - Should read 'rest of the EU'. 4.1 - Should clarify that this is for UK only clinical trials. RT reminded the group that the approved minutes would be published on the HRA website and that any requests for redactions should be sent to CB within two weeks of the meeting.
3.	**<u>Matters Arising</u>** **3.1 Terms of reference** RT asked for clarification regarding whether UKECA was still in existence to which JW confirmed that it was. PD asked for the acronym AHPPI to be correctly referenced as 'Association of Human Pharmacology in the Pharmaceutical Industry'. The group discussed whether the ToR should make reference to the role which the group has in relation to the EU CT Regulations and transparency. JMa highlighted that it is the MHRA who actually take the lead role regarding this work. It was agreed that an additional sub bullet point should be added to include other matters such as legislation and policy. JMa asked for the MHRA to be included on the list of representatives. JM asked whether point 2.4 was still relevant. It was suggested that this point could be worded more clearly as it could be any of the UK health departments which attends as an observer and not necessarily the Department of Health in England. It was agreed that the wording should be updated to say 'a UKECA nominated representative to attend the meeting as an observer'. The wording would be agreed and a revised version of the ToR sent round to agree as a final version. **Action: CB to distribute the updated version of the Terms of Reference to the group**. **3.2 Matters arising from February meeting.** Advertising clinical trial on job websites - Clive Collett CC fedback to the group that the HRA does not have a formal position in regard to advertising on job advert websites and the NREAP have not formally discussed the matter. The responsibility for making a judgement of appropriateness lies with the REC. JK added that some adverts for participation in a phase 1 clinical trial have been identified incidentally when appearing as though they were a job advert. When contacted, the people running the website have usually been willing to remove the advert. CC suggested that the broader philosophical question is whether participation in a clinical trial counts as work, or what other description would be most appropriate. It was noted that participation in a clinical

	trial does affect tax and benefits and is considered to be taxable earnings. AR suggested that a key consideration should be whether declining such 'work' could result in benefit penalties, in which case this could be considered to be coercive. If it could be seen as work and is declined there could potentially be a penalty. It was suggested that participants should be made aware of this as a possible issue, using the confidential helpline.
4.	**Update on the Clinical Trials Regulations** CB updated the group. The main activity since the Regulation was published has been around the EU portal/database. As per the Regulation, the EMA is responsible for developing and maintaining these systems in conjunction with Member States and Commission. A number of groups have been set up by the EMA, one of which is meeting with stakeholders. Following a short public consultation, the EMA finalised and published the functional specification for the EU portal and EU database in December 2014 and this is what the system will be independently audited against and thus the criteria that will be used to judge when an announcement may be made in the official journal which will set in place the count down to implementation of the Regulation. The Regulation states that implementation will be 2 years after publication in the official journal, unless the IT is not ready. Therefore the starting assumption is that the Regulation will be implemented in mid 2016, however, it would seem reasonable to expect that the earliest this could reasonably happen will be 2017. This is based on the functional specification just being published, however, the portal and database will still need to be built and tested before substantive audit and announcements can be made which would trigger the 6 month count down. The EMA have not however given an official timeframe. Other key development is the EMA's consultation on transparency rules, which once agreed will be an addendum to the functional specification. The next EMA meeting with stakeholders is 25 Feb 2015 and it is strongly suspected that the main agenda item will be the results of the transparency consultation. It is really important that if organisations have views they submit them by the 18 Feb 2015 deadline and do not leave until the stakeholder meeting.
5.	**<u>Transparency in Phase 1 research</u>** **5.1 EU CT Regulations & consultation - Janet Wisely** Paper copies of a slide set were distributed to the group. JW explained that currently the UK has an EU directive and extensive UK legislation in place which will be replaced by the EU Regulation. This will then require UK specific legislation and policy to support the EU Regulation and the intention is that the legislation will reference HRA policy as much as possible rather than the legislation being too detailed. The benefit of this is that it allows more flexibility. Once something is written into legislation it is very limiting and can't easily be changed if found to be unworkable in practice. Also, referencing HRA policy allows the opportunity to get the policy in place in advance of the implementation of the Regulation and thus reduces the burden of implementation. With regards to transparency, the aim of the Regulation set out by the EMA is that all information should be in the public domain unless there is a justifiable reason for it not to be. This includes everything which is provided as part of the application process and through ongoing reporting throughout the duration of the trial. The sanctions in relation to

	transparency will be on the same level as safety reporting. The intention is that all information will be publicly accessible unless all or part of data is deemed confidential. The functional specification is key and the proposal is that the process of publication is automated through the database. The expectation is that simple rules will be added into the functional specification so that information is published uniformly for all clinical trials. This is what there is the possibility to influence, as there will be no case by case decision making, just simple rules to apply. The MHRA and HRA have pushed the EMA for a deferral mechanism which means that information which could be considered to be commercially sensitive is not in the public domain until no longer commercially sensitive. The information which is expected to be publicly available at time of submission is the Main characteristics of the trial, Conclusion of assessment and decision, Start/end dates of recruitment, Substantial modifications, End date and later, summary of results, Clinical study reports once marketing authorisation granted, procedure completed or marketing authorisation withdrawn will be in public domain. The HRA and MHRA have managed to get a proposal into the consultation that for Phase 1 clinical trials involving healthy volunteers, there will be minimal information made public at the start and then an option of deferral from the end of the trial until the CSR is published. The HRA has signed up to the All-trials campaign so there is an expectation for registration and publication. However, the HRA accept that there are sometimes genuine issues of commercial confidence and have put in place a process to defer registration. The HRA registration deferral process is open to all clinical trials, including all Phase 1 clinical trials but the EU proposal is Phase 1 clinical trials involving healthy volunteers only. Therefore, the HRA policy is more generous than is expected to be allowed under the EU proposal. The HRA asks for confirmation that deferral is for reasons of commercial sensitivity but does not ask for any further detail than this. JW stated that on request, some CROs had provided more in-depth information in confidence regarding the decision to defer registration. 30 Detailed responses had been received and the areas of note were as follows: 1. Sponsor locations - a large number of non EU sponsors 2. 4 reference the sponsor policy as a reason not to register (for 2 of these they are non EU) 3. 5 referenced there being a patent pending The HRA will contribute to the MHRA in regard to their response to the transparency consultation. JW encouraged others present to provide similar information to the MHRA to support the view point that there should be a deferral option. JMa suggested that communication could be expanded to Phase 1 units which are part of the phase 1 unit accreditation scheme. SL explained that when this work had initially started, contact had been made with units on the accredited list of CROs. Approximately half didn't respond initially and they have been contacted again to encourage engagement. JMa said that she was happy to send some communication out. **<u>Action: JMa to communicate with Phase 1 units on the list of accredited units.</u>** JW highlighted that it had been identified in a recent audit that 79 Phase 1 clinical trials had

	not been registered and had not deferred registration via the HRA. If these CROs did however contact the HRA to defer then this would give more weight to the argument that the deferral process works and is accepted, which would benefit the cause to ensure there is a deferral process included in the EU Regulations. UL asked for clarification in regards to what would happen to organisations which do not comply. JW responded that they will initially be contacted to find out whether the clinical trial has started and if so whether they can either provide evidence of registration or explain why the trial has not been registered. The register which includes the trials which have not been registered, and there is no deferral in place, will be presented to the HRA Board which will mean that this information will be in the public domain. Administrative measures were also being considered. JW said that there was also some work being undertaken by Hugh Davies, HRA Ethics Advisor, looking at the ethical issues of using a previous history of non-registration to affect future decisions. Jim Elliott from the HRA was also doing some work with public involvement to get the viewpoint of patients and the public. JMo was having conversations with organisations such as the GMC as it may be that conduct sits better with professional bodies or employers. The Intended outcome of this work was to develop a set of proposed administrative measures to be consulted on and run in shadow form, which would prevent the MHRA having to use legal sanctions. JW added that the HRA would also like to celebrate compliance as well as deal with non-compliance. CA said that she would like to thank the HRA & MHRA for promoting the deferral process as part of the EU Regulation. CA asked how publication 12 months after the study has ended would be managed, would the EMA ask whether publication could now take place. JW responded that the EMA wanted simple rules which can be applied across the board, not to deal with trials on a case by case basis. JW suggested that it was important to choose which areas to try to change as trying to change too much could end up in no change at all, whilst choosing realistic areas to address could result in a viable outcome. CA asked for clarification on why Phase 1 clinical trials in healthy volunteers was referenced and not in patients. JW stated that the feeling was that this was deliberate and that it was very unlikely that this will be expanded to patients. Trying to change this was unlikely to lead to a positive outcome. JW said that a meeting had been held with All-trials to discuss the proposal and the agreement had been that whilst All-trials wouldn't actively support the proposal to defer commercially confidential information being in the public domain, they would not argue against it. It was noted that the decision regarding transparency needed to be made soon as it would need to be included in the functional specification as an addendum, specifically around the timelines for publication of information. UL asked for further clarification regarding the expected outcome of administrative sanctions. JW explained that the intended outcome was either registration or compliance with the deferral procedure as there was a great advantage in undertaking this work now to better understand the issues. Where non compliance is identified, the organisations will be contacted to find out why. This is a light touch approach in preparation for the EU CT Regulations. JM added that this work is crucial in building public confidence which is why the All-trials campaign have confidence in the HRA taking this work forward.

	AT asked whether a deferral of the publication of a research summary can be requested for any study. It was confirmed that this is the case but it should be noted that as the research summary is the wording in A6-1 of the IRAS form, the applicant has control over the content and therefore could be written in a way that it does not include commercially sensitive information. AR suggested that in regard to whether the REC could make decisions based on past behaviour, this is already done to some degree by reviewing the CV of the Chief Investigator. It was agreed that the REC did have a role to assess the suitability of the investigators and the site. The question is however, at what point does past behaviour mean that a new study is not given a favourable ethical opinion. It is hoped that the work being undertaken by Hugh Davies would provide some answers. It was suggested that better understanding of the status of the 79 studies which were not registered and there was no deferral in place would be helpful, particularly in terms of whether the sponsors are commercial or non commercial and their geographical location. CB agreed to get this information. **Action: CB to ascertain the geographical base of sponsors which have not registered and have not requested a deferral and also whether they are commercial or non commercial sponsors**. **5.2 EMA draft proposal on transparency vs HRA transparency policy** PD said that many of the questions put forward by the AHPPI members had already been answered during the course of the discussion. One issue did however continue to be that Phase 1 clinical trials in patients had not been included. Quite often single protocols will include both healthy volunteers and patients. PD asked for clarification regarding whether publication of the addendum by the EMA would affect the HRA proposal regarding previous registration. JW responded that the HRA intended to update the IRAS sponsor declaration to say that all clinical trials in active recruitment have been registered, or that a deferral is in place, from April 2015. It was noted that this was unlikely to affect Phase 1 clinical trials as it was unlikely there were any Phase 1 clinical trials which received a favourable ethical opinion before 30 September 2013 and were still in active recruitment. If any, they would more likely to be non-commercial studies. It was suggested that some NHS Trusts had said that they had started to look at ensuring that all actively recruiting clinical trials for which they are the sponsor are registered. Some Trusts have also expressed concern that this could be a big task but the view of the HRA is that if an organisation is sponsoring clinical trials, they should be able to identify which are currently in active recruitment and therefore it should be a manageable task. This will be monitored against by saying that a policy should be in place to ensure that all clinical trials in active recruitment have been registered rather than checking individual studies. These requirements are line with the requirements of the RGF. PD asked for clarification regarding whether the EMA is requiring this and whether other member states are also requiring this assurance. JW responded that the EMA have already taken steps to ensure registration of all CTIMPs via EudraCT since 2004. This initiative is about getting the public confidence and to promote registration for other clinical trials also. Clarification was requested regarding whether active recruitment meant in the UK only. It was confirmed that this did refer to the UK only and this would be explicit in the sponsor declaration.

	UL informed the group that she had attended a workshop held by the HRA on 5 February 2015 at which she had raised the issue of the legal basis for declaring that studies which received a favourable ethical opinion pre 30 September 2013 had been registered. It had been suggested at the workshop that this matter would be more appropriate for discussion at the Phase 1 Advisory Group. UL added that she had circulated a letter to the group which was from herself to the HRA. The letter set out concerns about using past actions to determine future actions and that consideration needed to be given as to whether this is lawful. UL referenced legal advice sought by Richmond Pharmacology and indicated that this may not be lawful as trials approved pre 30 September 2013 were approved under different conditions which could not be applied retrospectively. UL suggested that legal departments in organisations would be looking at this wording. JW explained that the sponsor declaration has included reference to the standards expected of a sponsor since 2008 and these expected standards and ethical principles have not changed. JW added that the greater concern is dealing with a legal challenge by a clinical trial participant who has been harmed as a result of the details of a previous clinical trial not having been registered in the public domain. The expectation was not that there would be a check of each individual study but that there was an appropriate policy in place. The requirements were in line with those of the Declaraion of Helsinki and the RGF. It was suggested that it would be important to establish how many Phase 1 clinical trials are still in active recruitment. JMa said that she would be able to provide an indication of this information by looking at which clinical trials received a CTA pre 30 September 2013 and had not yet declared the end of the trial. It was suggested that if the number of active Phase 1 clinical trials was zero, then it would be possible to say to sponsors in confidence that the declaration can be signed. It was however noted that some sponsors request that their legal teams look at all documentation and may not take such an assurance. **Action JMa - To provide a list of clinical trials which commenced pre 30 September 2013 and were not declared as ended.** AT also raised the issue of non CTIMP studies, particularly device studies where issues of confidentiality and patent were of concern. It was noted that the model Clinical Trial Agreement's requirements for registration of studies was more stringent than HRA requirements and very few issues had been raised by the devices industry. The ability to defer registration applied to all studies. **5.3 Outcomes of audit into compliance with the HRA deferral policy** CB updated the group in regard to the process for requesting deferral of the requirement to register clinical trials as well as the outcome of an audit which had been undertaken into Phase 1 clinical trials which had not requested a deferral but could not be located on a publicly accessible database. JW & JMo left the meeting.
6.	**Generic documentation** **6.1 Generic screening & 6. 2 Generic information sheets and consent forms which have already received ethical approval.** ChA updated the group in regard to work which had been undertaken to develop a template information sheet for non study specific screening. This had been suggested at the last

	Phase 1 Advisory Group and a sub group had since met to take the initiative forward. A draft template had been produced based on a number of different templates provided by CROs. The expectation was that this would be distributed to the sub group for comment shortly. There would then be a wider consultation of 3-4 weeks before a final document is agreed. This document will then be reviewed by the generic advert review committee and then can be used by all Phase 1 units without requiring any further ethical review. KB asked whether it would be possible to have a clear timeframe for guidance in relation to which generic documents should be reviewed and the process for submitting for review. RB added that Quotient Clinical had experienced problems with differing requirements from different RECs. She gave an example of the 'house rules' for the unit and that there was a potential for different RECs to request different changes which could result in one unit having slightly different house rules for different trials. RB asked whether there could be a generic review process for documentation other than adverts. CB stated that work had started on a policy for review of non study specific documentation but this was still ongoing. JK added that the previous process would continue to apply until this work was complete. If a document is being submitted to the REC which has already been reviewed by a different REC, this should be included in the cover letter so that the second REC should not request any further changes, unless they felt it was of significant importance. If any problems are experienced regarding this, it should be fedback to NRES to look into the matter and hopefully resolve. The group discussed whether documentation which is not to be reviewed by the REC should be included for 'information only'. There was a split view with some REC Chairs saying that they prefer all of the documents for context, even if they are not expected to review certain ones and other Chairs said that if they don't need to review something they would rather not receive it at all as it just adds to the large number of documents received. JMa explained that this issue had originally been raised as it was identified through GCP inspection that a number of different screening documents appeared to be used and that alignment would have been beneficial. JMa said that she was of the view that any document which did not require REC review should not be submitted to the REC for information. RT asked whether it would be possible to use the existing generic documentation review committee to review all non study specific documentation. CB explained that this was largely an issue of resource and the increased volume of work would need to be scoped before confirming whether this would be possible. There are only three members of the Committee and this work is additional to their substantive REC. It was agreed that information regarding the documents involved would be undertaken in the first instance to get an idea of resource implications. It may be that a number of templates could be produced to reduce the need for review on behalf of each individual unit. It was agreed that in the interim period, RECs would be reminded that if the cover letter states that a document has been reviewed by a different REC, the document does not need to be reviewed again. Commencing clinical trials should not be delayed due to re-review of already approved documents. UL asked for clarification regarding diary cards as this had previously been raised at a meeting but was still unclear. JMa explained that anything which the participant completes after they have been consented should be submitted to the REC, this included diary cards but did not include CRFs. The format of the documents does not need review but the content did. The review sub committee would pick up this matter.

	Action: ChA to send out a communication to REC Chairs regarding what is expected of the REC when documents have already been reviewed by another Committee.
7.	**Seven Day Submission** CB informed the group that a review had been undertaken of the 7 day submission option to assess the acceptance by REC members. The feedback received had been positive with no concerns highlighted. Some RECs had not previously accepted applications up to 7 days before the meeting but had now agreed that they would. AB asked how many applications had been submitted to this timeline. CB explained that this could be ascertained from the Management Information provided by referring to the column entitled 'Number of days submission to review'. Any numbers which are approximately 7 -10 would be considered to be a seven day submission as agreement would have been made with the REC Manager to submit to this timeframe. Post meeting note: The total was approximately 16 over the 12 months period.
8.	**Phase I Management Information Data** CB introduced the MI and explained the data within each column. 8.1 By CRO (1.10.13 - 30.9.14) 8.2 By REC (1.4.14 - 30.9.14) 8.3 By REC (1.10.13 - 31.3.14) JK suggested that it would be beneficial to look at the reasons for the provisional opinions which had been given to better understand the reasons for this. The group agreed that the MI data was useful and that they wanted to continue to receive it. **Action: CB to look at the reasons for provisional opinions given for Phase 1 clinical trial applications.**
9.	**Retaining data on TOPS** ChA updated the group in regard to TOPS. TOPS holds a record of participants from Phase 1 clinical trials going back a number of years. There had been discussion regarding whether this information may now be deleted as may no longer be considered as being held for a stated purpose and therefore is being retained longer than absolutely required. However, concern has been voiced regarding studies involving Monoclonal Antibodies (Mab) where it could be argued that the stated purpose may justify indefinite retention. The new TOPS has the functionality to state whether the subject has had a Mab so going forward the HRA would only need to retain these records, but the historic records do not distinguish. There are likely to be low number of subjects affected but they cannot be identified. JK advised that she had spoken with staff in the Confidentiality Advisory Team who had advised an argument could be made either way. It was noted that there was no firm evidence to say what period after taking part in a clinical trial involving a Mab a participant should wait before taking part in another clinical trial, or how many Mabs a person can take in their lifetime. It was highlighted that some protocols do however exclude any participant that has previously received a Mab. In these cases, it would be necessary to know whether all participants had ever received a Mab and this would require data on participants that receive a Mab to be held indefinitely.

	PD highlighted that for some bio-similar studies there is a suggestion that the participant should not have the same Mab twice. It is therefore important to know what Mab a participant has received as well as when they received it. It was queried how this detail would be collected and confirmed that this would have to be by contacting the unit directly to request the information. It was noted that there are two issues, what the actual impacts of receiving a Mab are, which is largely unknown, and how to deal with the situation when a protocol excluded any participant who has previously received a Mab It was further noted that this was not an issue for entries on the new TOPs as this information was now collected and all other records could be erased after a two year period. KB suggested that it would be helpful if it was clearer on TOPS when a record relates to a study which involved receiving a Mab, such as the screen turning red as an alert which couldn't easily be missed. ChA agreed to add this to the considerations to include in the next TOPS update. ChA was also asked whether a change could be made so that a date could be added for the long term follow up instead of a time period, it was confirmed that this would also be given consideration in the next update of TOPS. It was queried whether the record would still be visible after the long term follow up period has passed and confirmed that it would not. It was therefore suggested that this should be made clearer in the supporting guidance, particularly as some units are using TOPS and may be unfamiliar with the process. **Action: ChA to update the specification for the next TOPS improvement.** PD informed the group that he was due to attend a meeting at which the issue of Mabs would be discussed and agreed to feedback to the group. It was agreed that once more scientific information was known it would be easier to assess the importance of the issue regarding retention of historic records. If it was identified as a significant issue then there may be a case for units to go back and check which Mab studies they have undertaken and update the record of each participant who took part. This way, only historic records for participants who received a Mab would be retained. **Action: CB to add to the agenda for next P1AG meeting**
10.	**Travel insurance** The group discussed the issue that concern has been raised regarding problems with getting travel insurance for participants in Phase 1 trials. Advice had been sought from the Association of British Insurers but they have not yet responded (to Clive Collett). The guidance is not explicit regarding whether participation in a phase 1 clinical trial should be mentioned when getting travel insurance. CC informed the group that he had contacted the ABI to point out that the guidance was out of date and they agreed to update it. This was in September 2013 and the guidance had not been updated so far. Will Bowen from the HRA is meeting with the ABI and will feedback to the group. **Action: CB to add to the agenda for next P1AG meeting**

11.	**Gateway to phase 1 clinical trials** The group discussed the following issue: In the Patient and Public Involvement part of the new site, the HRA have a section about finding out more about clinical trials for those people that are interested in joining a study. For patients we have a link to the NIHR clinical trials gateway. At the moment there is no gateway link for people wanting to join a Phase 1 study. It was queried whether there is a generic all-encompassing gateway for Phase 1 studies. If that is the case then the only thing we could do is link to individual company/NHS sites. The group were asked to comment on whether this would be a)feasible and b)politically acceptable? JMa highlighted that there is already a website called 'rate my clinical trial' which gives information about phase 1 clinical trials, however JK suggested this did not provide the necessary information and was similar to Trip Advisor. RT suggested that a link could be added to give information about MHRA accredited Phase 1 units. It was also suggested that as all of these solutions are web based, it would be just as easy to type 'how to volunteer in a clinical trial' into a search engine and find this information, without adding additional signposts.
12.	**Any other business** 12.1 **Phase 1 information on the HRA website** CB updated the group that a Phase 1 section was being designed for the website. The content had been written and was being reviewed by the communications team but should be available soon. This section would include the minutes of the Phase 1 Advisory Group, the Management Information data, ongoing initiatives regarding Phase 1 clinical trials and phase 1 transparency. CB agreed to send a link for the Phase 1 section of the website when it was complete. **Action: CB to send link for the Phase 1 section of the website to all members of the group.** 12.2 **Consistency** A paper on consistency of REC review which had been produced by the National Research Ethics Advisor's Panel was distributed to the group for information. JK asked the group to take particular note of the initiative already in place. JK asked the group to provide any feedback in regard to consistency of REC review which they experience to the HRA so that it could be looked into. JK explained that the RECs take part in a Shared Ethical Debate which is where a number of RECs review the same, previously reviewed application to assess consistency of review. It was noted that Phase 1 applications have not been used as permission has not been granted for an application to be used. JK encouraged granting permission so that a Phase 1 application could be used in the scheme. It was suggested that a non commercial Phase 1 study may be most likely to be granted permission. AR raised the issue of some REC Managers giving incorrect advice regarding the use of favourable with conditions which had resulted in a higher rate of provisional opinions which had been unnecessary. JK acknowledged that for some more inexperienced staff this could be the case and it was intended to provide further training. AB requested that this be joint training for REC Chairs

	JMa highlighted that as part of the MHRA inspection, they also look at whether conditions have been met and if have not then there would be a finding. JMa requested that when it was identified that conditions had not been met then inform the MHRA. DC suggested that more could be done regarding giving recommendations rather than requiring changes. JK stated that historically the HRA had been advised that industry did not like recommendations as they are often not clear and can cause confusion. 12.2 **Publication of the summary of opinion** SL asked when the publication of the summary of the REC opinion is expected to commence. JK informed the group that it had been agreed that the HRA will not publish this as standard as the number of hits on the website had been low and the resource that went into formatting the summary ready for publication is high. If someone wanted a copy of the summary of opinion for a study, then this could be provided on request. The expectation was that the need for automatic publication would be assessed depending on the volume of requests. 12.3 **REC staff attending units to talk to staff.** JK highlighted that one CRO had changed staff and it was thought would benefit from REC staff attending the unit to talk to them. If any units wanted to arrange for someone to attend and talk to staff, they could contact the HRA for this to be arranged.
11.	**Date of Next meeting** 30 June 2015 HRA1 Skipton House, London