FOUR NATIONS MEETING
MINUTES

Minutes of the Four Nations Meeting, held on Tuesday 20 January 2015 from 1.00pm – 4.00pm in HRA 1, Skipton House / via teleconference

Present	Initials
Janice Bailie, Health and Social Care Research & Development	**JB**
Sandor Beukers, Medicines and Healthcare Products Regulatory Agency *(in part, 1-4)*	**SB**
Sue Cartwright, Department of Health	**SC**
Louise Dunstan, National Institute for Social Care and Health Research	**LD**
Jonathan Fennelly-Barnwell, Health Research Authority	**JFB**
Janet Messer, Health Research Authority	**JM**
Alex Newberry, National Institute for Social Care and Health Research	**AN**
Tom Smith, Health Research Authority	**TS**
Mike Stevens, Chief Scientist Office	**MS**
Stephen Tebbutt, Health Research Authority	**ST**
Martyn Ward, Medicines and Healthcare Products Regulatory Agency *(in part, 1-4)*	**MW**
Janet Wisely, Health Research Authority	**JW**

Item	Item details	Action
1.	**Apologies** None to note JW welcomed MW and SB to the meeting.	
2.	**Minutes** The group agreed the minutes of the previous meeting were an accurate representation of the matters discussed with the following amendment: - Addition to Page 4, Item 4.3 *ST agreed to provide a final decision for any membership queries.*	
3.	**Matters arising** <u>Non-Commercial sponsor group</u> The group noted the terms of reference had been circulated. <u>Allocation of costs</u> The group noted JW had relooked at the principles for the allocation of costs, especially IRAS, with the proposal to split by the proportion of the ethics component in each country. Debbie Corrigan, HRA Director of Finance, is taking forward and will be in touch with DAs in the near future. <u>Compatibility group update</u>	

	JM advised the new process for the management of amendments would be launched in a discreet manner. A teleconference is due to take place in late January however this had not been scheduled as yet. At this point consideration regarding making a larger broadcast would take place.	
4.	**UKECA Business** <u>Update on Clinical Trial Regulations and UK legislation to enable implementation</u> SB advised discussions had been held between the HRA, the MHRA and DH to discuss the EU Clinical Trial regulations and their impact on the UK legislation for RECs. UKECA was supportive of the preference of maintaining UKECA and referring to this in the new policy framework to minimise the need to detail information on the face of UK legislation. UKECA noted there were some definitions which may differ between countries however this is a minor issue which should easily be resolved. MW gave an overview of the status thus far. UKECA noted the likely implementation date was mid 2017 based on the IT development requirements. MW flagged the UK is represented on all IT working groups. MW advised the current expectation is for the EU system to be agreed in March with the specification to be available from then onwards to allow us to begin work on our systems. UKECA noted a consultation is due to begin tomorrow regarding the application of transparency rules for the EU Clinical Trial Regulation. UKECA noted a response on behalf of the UK would be provided. <u>Potential sanctions for breach of transparency conditions</u> UKECA noted UK wide agreement was sought for the establishment and oversight of a project to gather views on potential administrative sanctions that may be set out within research policy in the UK, and implemented alongside the clinical trial regulations. UKECA noted two pieces of work had been proposed to support this proposal: 1. Led by Jonathan Montgomery, HRA Chair, to seek views, input and support from professional and regulatory bodies such as, but not limited to, the British Medical Journal, the General Medical Council and the Royal Colleges. 2. Led by Hugh Davies, HRA Ethics Advisor, to work with REC Chairs / members in order to ascertain the view of REC members on what sanctions may be appropriate and which body should apply such sanctions and specifically the ethical considerations and 'appetite' of the REC community of using the REC opinion as a potential sanction point A wider audience would be involved from March to May based on the findings from the above groups with a view to a recommendation being made to UKECA on 26 May. JW flagged she had increasingly been asked by REC members and Chairs regarding	

	what their role will be. MS raised the potential concern of UK being seen to apply the sanctions 2 years ahead of the requirement under the Clinical Trial Regulations. UKECA agreed the term 'sanction' should be replaced with 'administrative measure' until the legislation comes into effect. UKECA was supportive of Jonathan Montgomery seeking the views from professional and regulatory bodies. UKECA agreed the event led by Hugh Davies should focus on the ethical issues of applying measures rather than the role of the REC in applying those measures and agreed the event should be England focused however members from other countries would be welcome to attend. <u>Target timeline for review of Phase 1 clinical trials</u> UKECA noted the proposal to set demonstrable targets for the time period between the meeting and the initial opinion and, for provisional opinions, between receipt of the response to provisional and issuing the final opinion. This can then be highlighted to potential global sponsors to demonstrate what the UK ethics service can deliver. UKECA noted the proposed timeframes are based on timeframes currently achieved by some RECs. MS highlighted this was a policy issue and challenged the proposal and advised complaints are not frequently received with regard to the current timelines. UKECA noted a meeting will be conducted via teleconference to map the process and identify the potential issues, risks, impacts etc. with the intention of developing an effective process to deliver shorter timeframes for Phase 1 clinical trials but not making it a policy requirement at this stage. A communication strategy will then be devised to ensure that global sponsors are aware of the service provided by the UK. UKECA discussed the proposed timelines and agreed they could be met in some instances however questioned what would occur for complex studies where greater consideration is required to avoid compromising the standard of service. UKECA however agreed it could be a useful selling point if the UK could demonstrate a commitment to providing a first decision within 6 working days. UKECA noted any potential charging would need to be integrated within the MHRA fee as only one charge is allowed per member state. <u>Audit and Accreditation update</u> UKECA noted the RECs discussed at the last meeting had all shown good progress with their action plans and agreed their recognition statuses should be maintained. UKECA however agreed if there are any future issues the process for resolution should move quickly to the more stringent measures. *MW and SB left the meeting*	
5.	**HRA Collaboration & Development Programme Update**	

	Single Technical Pharmacy Review (STPR) JM advised the STPR had been well received with 28 studies from the Experimental Cancer Medicine Centres (ECMC) in process with 19 completed. It had been estimated that approximately 300 hours of pharmacists' time had been saved so far. The group noted queries had been received from pharmacists outside of England regarding what will happen when the assurance is extended which requires further consideration. Workshops would be planned for pharmacists outside of the ECMC network. Radiation assurance The group noted the process would be tested with the ECMCs, as per the pharmacy assurance. JM advised the same general principles applied with people interested in the outcome and the impact more widely. The DAs were interested in the pharmacy and radiation workshops and agreed to identify people to attend. The group agreed it would be sensible if Non ECMC pharmacy leads attended with their own R & D people to allow leads to receive the same information from the beginning. The group agreed it would be beneficial to bring together a group from across the DAs to consider how the process could work. HRA Approval update JM advised the programme continued to progress with some 'dummy runs' conducted to inform the development of standing operating procedures. Consideration of implications for cross-border studies would also take place. Model Non-Commercial Agreement (mNCA) The group noted the agreement had been circulated for comment. The comment period is due to end on 3rd February. Information for sites JM advised consideration of the information for sites and a potential move away from the SSI form was being considered. A template is in the early stages of being explored which could allow the sponsor to provide the information they know before working with the site to obtain the relevant information required. More information would be shared later in the year to enable initial conversations to be held. Liability JM advised a meeting had been held with the NHS Litigation Authority which was content with our approach and proposals subject to a few minor adjustments. Research passports The group noted the issue relating to primary care was an English specific issue. The group discussed its appetite for considering the research passport package as a whole however agreed it was more appropriate to finalise the work to replace the Research Governance Framework at this time.	
6.	**HRA update**	

	Social Care listening event JW advised the HRA was hosting a listening event for social care researchers on 24th February. AN advised a similar exercise will be required in Wales. AN and LD agreed it would be helpful to observe the event in England.	
7.	**Department of Health update** NDPB Status SC congratulated the HRA on its establishment as a Non-Departmental Public Body. Sponsor team SC advised Richard Carter had taken over from Simone Bayes whilst she is on maternity leave. SC advised Lisa Smedley is leaving the team with a replacement to be identified in the near future.	
8.	**Update from Northern Ireland** Strategy consultation JB advised the consultation had closed on 2nd January with approximately 40 responses received. Director of R & D JB advised the post was yet to be advertised.	
9.	**Update from Scotland** Health Research Strategy MS advised the strategy would likely be published in the first half of this year. SHARE MS advised over 50,000 people had registered on SHARE, the new NHS Research Scotland initiative to establish a register of people interested in participating in health research and who agree to allow SHARE to use the coded data in their various NHS computer records to check whether they might be suitable for health research studies. NRS Central team arrangements MS advised the central team arrangements went operational from 1st December 2014 with the industry liaison post to move across from 1st April 2015. Replacement for Graeme MS advised a replacement for Graeme had yet to be identified.	
10.	**Update from Wales** National Institute for Social Care and Health Research (NISCHR) infrastructure AN and LD advised the restructuring of the infrastructure continued. HRA Approval AN and LD advised consideration of what HRA Approval will mean for Wales is	

	beginning to take place with a project plan in the process of being developed. <u>New Governance Structure</u> AN and LD advised advanced discussions were taking place as to whether a Chief Operating Officer or Delivery Director in a national role would be required however a specific NHS delivery board would be created.	
11.	**UK wide arrangements for IRAS and HARP** JM advised specified individuals in each Devolved Administration would be able to have access to the HARP database to have sight of the information going into HARP for HRA Approval purposes. This will include the ability to search on particular items and view certain aspects. This had been developed for pharmacy and radiation leads however there could be benefits if extended across R & D. The group however agreed it would be important to define what would be made visible.	
12.	**Any other business** <u>UK Policy Framework for Health and Social Care Research</u> The group noted the document would be considered at the HRA Board meeting tomorrow. An updated version would be shared with colleagues towards the end of the week to allow ministerial briefings to be drafted with the aim for the comment period to begin by the next HRA Board meeting on 16th February. <u>Delegated decision making to UKREDG</u> The group discussed the proposal to consider how business is aligned between the UKECA / 4 Nations meeting and what business is conducted at UKREDG including issue relating to policy such as the target timeline for review of phase 1 clinical trials earlier on the agenda. A paper will be brought to the next meeting. ***Action: ST and JW to draft proposal***	**ST/JW**
13.	**Date of next meeting** 31 March 2015, 1pm – 4pm, HRA 3 / teleconference	