FOUR NATIONS' MEETING
MINUTES

Minutes of the Four Nations' Meeting, held on Tuesday 5 August 2014 from 1.00pm – 4.00pm in HRA 2, Skipton House via teleconference

Present		Initials
Janice Bailie, Health and Social Care Research & Development		**JB**
Simone Bayes, Department of Health		**SB**
Claire Bond, National Institute for Social Care and Health Research		**CB**
Graeme Campbell, Chief Scientist Office		**GC**
Joan Kirkbride, Health Research Authority		**JK**
Janet Messer, Health Research Authority		**JM**
Alex Newberry National Institute for Social Care and Health Research,		**AN**
Stephen Tebbutt, Health Research Authority	*(Secretariat)*	**ST**
Janet Wisely, Health Research Authority	*(Chair)*	**JW**

Item	Item details	Action
1.	**Apologies** Louise Dunstan, National Institute for Social Care and Health Research (LD) Mike Stevens, Chief Scientist Office (MS)	
2.	**Minutes** The group agreed the minutes of the previous meeting were an accurate representation of the matters discussed with the following amendment: - Page 4, first paragraph: *The group noted these variations were one area HRA Assessment and Approval would look to make more consistent across the country.*	
3.	**Matters arising** <u>Finance charges 2014/15</u> The group noted the meeting to discuss the finance charges for 2014/15 between Debbie Corrigan and the devolved administrations (DAs) was scheduled to take place on Thursday.	
4.	**UKECA Business** <u>MoDREC update</u> The United Kingdom Ethics Committee Authority (UKECA) noted it had delegated responsibility for the monitoring of the review of Clinical Trial of an Investigational Product (CTIMPs) for the Ministry of Defence Research Ethics Committee (MoDREC). UKECA noted MoDREC had reviewed two clinical trials over the past two years. UKECA noted it requires NHS Research Ethics Committees (RECs) to	

	review a minimum of approximately 15-20 applications over a two year period to ensure member expertise is maintained. JK advised she had met with the Surgeon General, a member of the Surgeon General's team and the Chair of MoDREC to discuss this issue. UKECA agreed there is a need for MoDREC to continue with its recognised status to review CTIMPs due to the exceptional and sensitive nature of the CTIMPs involved. UKECA noted MoDREC members are required to have detailed security checks prior to joining and the committee followed a very rigorous review process. UKECA noted MoDREC flagged it anticipated reviewing a greater number of CTIMPs over the coming year. UKECA agreed MoDREC could continue to review CTIMPs however agreed the following measures should be undertaken to ensure expertise and maintain assurance for UKECA: 1. Co-option of two experienced NHS REC Members when CTIMPs reviewed 2. Confirmation of membership to identify number of current and former NHS REC members with experience of reviewing CTIMP studies 3. HRA to be invited to any meeting where CTIMP studies were reviewed 4. Confirmation that MoDREC was meeting legal timelines 5. HRA to audit review process for each CTIMP study 6. HRA to assist with training programme for MoDREC members 7. MoDREC to participate in Shared Ethical Debate UKECA agreed to delegate the review of membership (point 2 above) to JK. JK flagged she did have some concern with regard to timelines (point 4 above) as amendments were reviewed by full Committee rather than sub-committee as per normal practice for NHS RECs. JK advised MODREC had agreed to provide further details on timelines.	
5.	**Clinical Trials Regulation** The group noted the implementation of the regulations will not take place until at least a year after HRA approval. However the group noted there had been early discussions at an operational level at United Kingdom Research Ethics Development Group (UKREDG) regarding how the new regulations might be implemented.	
6.	**HRA Collaboration & Development Programme** <u>Recruitment</u> The group noted recruitment was ongoing. Two people were now in post with more to join throughout August and September. <u>Single pharmacy review</u> The group noted good progress has been made with regard to the pharmacy project. The next Cancer Research UK (CRUK) study ready for review will test out the new process where one pharmacist is nominated to undertake a full review which pharmacists at other sites will rely on, allowing them to concentrate on the	

	local aspects of the study for their site. In the longer term this assessment would allow the sponsor to input the correct information into the application form and protocol prior to submission. The group noted the pilot involved the Experimental Cancer Medicine Centre (ECMC) Network with pharmacists from the DAs taking part. GC flagged a single pharmacy review was already in place in Scotland. AN and JB advised there was no system in place in Wales or Northern Ireland and were keen to see the outcome from this initial piece of work. <u>Single radiation review</u> The group noted a meeting is scheduled for 15 September 2014 involving the small group leading the work with other radiation professionals with the intention of forming a wider cohort of experts which could be used to more formally consult on the proposed guidance. The group noted good support had been received from the Institute of Physics and Engineering in Medicine regarding the proposals. The group noted the ECMC network was intended to be used for this proposal. JM requested DAs to contact her if there are any additional people they would like to be involved in the proposal. ***Action: DAs to contact JM with any additional radiation experts***	**DAs**
	<u>Model Non-commercial agreement</u> JM advised a further round of discussions had taking place involving Universities and NHS organisations with the comments currently being collated. JM advised the updated version of the agreement would likely be ready for review at the September Four Nations meeting.	
7.	**Research Governance Framework Update** <u>Responses to RGF consultation on perceived risk</u> The group noted the summary of feedback received. The group agreed there may need to be expectation management with regard to some of the proposals made. The group noted this would be picked up at the next Research Governance Framework (RGF) steering group meeting.	
8.	**HRA update** <u>Organisational structure</u> JW advised the consultation had now closed for those staff affected by the reorganisation of the director level functions. The new structure will be published and available for DA colleagues to view from next week. <u>Director of Systems and Development</u> The group noted this post was currently out for advert with the interview to take place on 12th September. JW advised she would not be involved in the panel however Jonathan Montgomery would Chair the panel and AN had agreed to sit on the panel alongside Debbie Corrigan and Carol Jones. <u>Transparency consultation</u> JW advised the consultation had now closed with approximately 200 responses received. The group noted the comments were largely positive. One area of	

	concern related to the possibility of other European countries not demanding the registration of clinical trials as required by the Clinical Trial Regulations and the UK, having made the changes, being at risk. The group agreed to have a discussion regarding this concern at a future meeting however noted since 30 September 2013 the HRA has required, as a condition of the favourable REC approval, that clinical trials be registered on a publicly accessible register within 6 weeks of first participant recruitment in the UK. To date very few requests to defer have been received. The group noted the Medicines and Healthcare products Regulatory Agency (MHRA) is leading on this subject and any comments should be forwarded to Sandor Beukers. ***Action: ST to add registration of CTIMPs and concerns to future agenda*** JW advised the next transparency workshop will take place in September. <u>Identification of research participants</u> JW advised the HRA was conducting a piece of work to identify whether or not the HRA has approved studies which could potentially be subject to criticism regarding who has been allowed access to notes to identify potential participants. JW advised a set of scenarios has been developed and agreed to share with DAs. ***Action: JW to share scenarios with DAs via ST*** The group agreed this is a sensitive issue which requires further work. JW advised the funding from Sciencewise will partially look at access to data for research. The group noted Mark Taylor, CAG Chair was supporting this work.	**ST** **ST**
9.	**DH update** <u>Care Act 2014</u> The group noted the Care Bill had now been passed which would allow the HRA to become a non-departmental public body (NDPB) in this parliament which is the stated intention. The establishment of the HRA as a NDPB will require appointments to the new HRA Board. <u>R & D Director</u> SB advised Russell Hamilton was likely to return to work in Mid-August. <u>Clinical Trial Performance</u> The group noted the National Institute for Health Research (NIHR) has, since 2012, required (new) NHS contractors to report performance on the initiation and delivery of clinical trials. This includes the benchmark of 70 days or less from the time a provider of NHS services receives a valid research application to the time when that provider recruits the first patient for that study. The reporting requirements are being significantly extended across the NHS in England in 2014/15 with new NIHR Local Clinical Research Network (LCRN) contracts. In future, NIHR funding to providers of NHS services will be conditional on meeting the 70-day benchmark to recruit first patients for trials. SB advised that a cautious approach was to be taken for the first year: after Q2, the ~50 organisations that have been reporting since at least Q3 2013/14, and who have performed most poorly and shown least improvement, will have a small reduction made to their NIHR Research Capability Funding in 2015/16. <u>NIHR Clinical Research Network Coordinating Centre</u> SB advised an invitation for the provision of the NIHR Clinical Research Network	

	Coordinating Centre was currently out for tender with the new function to be in place from April 2015, replacing the current contract.	
10.	**Update from Northern Ireland** Director of R & D JB advised the Director of R & D had recently left the organisation with a replacement still to be appointed. R & D Strategy JB advised this would likely be issued for consultation towards the end of August. Visit from DA colleagues JB advised colleagues from Wales had visited recently with colleagues from Scotland scheduled to visit this week to look at putting into place greater industry liaison. Dementia Care JB advised work was taking place in conjunction with Atlantic Philanthropies to help fund dementia care research.	
11.	**Update from Scotland** Chief Scientist Office Health Research Strategy GC advised the closing date for comments on the strategy is 30th September 2014. GC advised the new strategy will hopefully be launched at the NHS Scotland Conference in November. The strategy is available here: http://www.cso.scot.nhs.uk/wp-content/uploads/CSO-Health-Research-Strategy-30-June-2014-Draft2.pdf. GC flagged one area in particular for the group to note; the creation of an NRS General Manager with a small support team collectively working as the NRS General Manager Services (NRS-GMS). The group noted they will undertake the high level co-ordination of NRS activities and specific NRS operational functions previously undertaken directly by the NHS or Chief Scientist Office (CSO), including budgetary aspects. NRS permissions system GC advised a discussion will be held in the near future with the NHS Strategy Board regarding proposed changes to generic review which is similar to global governance checks in other countries. GC advised a distributed model was currently in place with the intention of formalising this process. Dedicated individuals in four NRS nodes to conduct these reviews will be required.	
12.	**Update from Wales** R & D office review AN advised the review had now been completed with a report received from the consultant responsible for conducting the review. A response from the National Institute for Social Care and Health Research (NISCHR) is expected shortly. AN advised the consultant, Nicky Williams, has been tasked to conduct a further piece	

	of work to look at integrating the R & D NISCHR support centre and NICHSR workforce with the aim of having closer regard to decision making and accountability. <u>Biomedical Research Centre / Units competition</u> AN advised NISCHR had announced a call for expressions of interest for proposed Biomedical Research Centres / Units with a panel to meet at end of September to make a decision on the successful sites.	
13.	**R & D Compatibility Group update** The group noted the last meeting had been held in July. <u>Amendments</u> AN advised a teleconference between operational colleagues will be held to make final adjustments to the cross border amendments process. The group noted this work intended to be ready to be launched in October with appropriate lead in time to be arranged. <u>HARP access</u> The group discussed the potential quick win of opening access to relevant documentation via the HRA Assessment Review Portal (HARP) for colleagues across the DAs to allow better integration between RECs and R & D and support UK wide working. The group considered how best to manage the UK wide element of HARP and the Integrated Research Application System (IRAS). One option would be to have a UK wide lead to sit on both the IRAS and HARP Boards. The DAs agreed to consider and discuss at the next meeting. ***Action: UK Wide arrangements for IRAS and HARP Boards to be considered by DAs and discussed at next meeting***	**DAs**
14.	**Any other business** None to note	
15.	**Date of next meeting** 23 September 2014, 1pm – 4pm, HRA 1 / teleconference	