FOUR NATIONS' MEETING
MINUTES

Minutes of the Four Nations' Meeting, held on Tuesday 23 September 2014 from 1.00pm – 4.00pm in HRA 1, Skipton House via teleconference

Present		Initials
Janice Bailie, Health and Social Care Research & Development		JB
Simone Bayes, Department of Health		SB
Bill Davidson, Department of Health		BD
Graeme Campbell, Chief Scientist Office		GC
Louise Dunstan, National Institute for Social Care and Health Research		LD
Janet Messer, Health Research Authority		JM
Mike Stevens, Chief Scientist Office		MS
Stephen Tebbutt, Health Research Authority	*(Secretariat)*	ST
Janet Wisely, Health Research Authority	*(Chair)*	JW

Item	Item details	Action
1.	**Apologies** Alex Newberry, National Institute for Social Care and Health Research (AN)	
2.	**Minutes** The group agreed the minutes of the previous meeting were an accurate representation of the matters discussed with the following amendment: - Page 2 – Minor typographical correction - Item 12 – Update from Wales *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.*	
3.	**Matters arising** <u>Break in service for Research Ethics Committee (REC) members</u> JW advised the recruitment and selection of REC members policy was being updated to detail how a managed return will be followed when a member returns to a REC after a period of extended leave. The group noted this will involve a meeting with the appointing authority lead. <u>Identification of research participants</u> At the last meeting 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. The group noted Amanda Hunn was leading this piece of work. Finance recharges for Devolved Administrations (DAs) The group noted a meeting between the DAs and Debbie Corrigan, HRA Director of Finance, had been held with the finance recharges agreed for this year. A further meeting will be held in November to discuss the recharges for 2015/16. Agreements between DAs and the HRA BD advised DH lawyers have confirmed the agreements would not require renegotiating once the HRA becomes a NDPB. GC queried if the review point for the agreements had passed and the group agreed to discuss at the next meeting. ***Action: Agreement review point to be added to November agenda***	**ST**
4.	**UKECA Business** None to note	
5.	**Clinical Trials Regulation update** None to note	
6.	**HRA Collaboration & Development Programme** HRA Approval The group noted the gateway review to provide assurance regarding the programme was currently in progress with a report to be provided on Thursday. Single pharmacy review JM advised the single pharmacy review has begun with Cancer Research UK (CRUK) giving positive feedback. Refinements of the process will take place as the roll out progresses. The group noted CRUK planned to issue a press release to the pharmacy world regarding the project. Single radiation review JM advised a meeting was held on 15th September with a group of radiation professionals with useful discussions taking place. Further work will begin to consider what future guidance might look like and how a wider consultation could take place. In the immediate future, work to update the guidance on the HRA website will begin. JM advised Sue Bourne is leading this area of work. JB and JW agreed it would be useful to add a presentation from Wendy Fisher to the event in Northern Ireland in October. Information Governance The group noted Mark Taylor, the Confidentiality Advisory Group (CAG) chair, was taking forward work regarding how NHS organisations can be assured that they do not need to do their own assessments, as part of his secondment to the HRA. The group noted Mark had been in touch with colleagues in Scotland regarding their experiences. Model non-commercial agreement The group noted this was almost finalised and would be brought to the following	

	meeting for discussion. Research passports The group noted the pilot conducted by NHS England and DH with the support of the NIHR Clinical Research Network (NIHR CRN) and the HRA to test a single operating model for issuing Honorary Research Contracts (HRCs) and Letters of Access (LoAs) to researchers undertaking research in primary care should be published in the next few months. The group noted the future consideration of a single contract approach for secondary care had been discussed with NHS England with the management of the UK wide framework requiring greater contemplation. The group agreed an item on secondary care single contract approach be added to the agenda for the next meeting. ***Action: ST to add research passports – secondary care to November 2014 agenda*** Research support functions following implementation of HRA Approval The group noted a paper providing clarity regarding what activities the HRA would not be responsible for when HRA Approval is implemented would be made available on the HRA website in October. Non-Commercial sponsor group The group noted a group of non-commercial sponsors had been established with an interest in taking forward the sponsor toolkits and sponsor training work. The first meeting will take place shortly. JM advised only sponsors from England were currently members and asked DA colleagues to advise if they wished to have representation on the group. Application managers work JM advised the application managers had begun work to consider complex studies. In particular the managers had been looking at bioresource and handling of tissue. Protocol templates The group noted the templates would likely be released for use for clinical trials (commercial and non-commercial) at the end of October / beginning of November with feedback to be sought prior to release for wider studies.	**ST**
7.	**Research Governance Framework Update** None to note	
8.	**HRA update** Director of Systems and Development The group noted JM had been appointed as the Director of Systems and Development. JW advised part of the recruitment process involved a presentation from candidates to patient representatives, as set out previously in the HRA's Patient and Public Involvement strategy. JW advised this would be repeated for senior roles and other relevant posts. Transparency The group noted there had been a good response to the call for comments on the reporting, publication and REC declaration requirements and the HRA has agreed	

	to proceed with the proposals to update the REC declaration. The group noted the next steps were discussed at a workshop on 18th September and a date has been set for a further workshop in February. The REC declaration will be updated in September and again in April in line with the proposals set out. Chief Scientist Office (CSO) and HRA workshop in Edinburgh JW advised a very useful meeting had been held with JW and Wendy Fisher presenting an overview of the HRA and its functions; with a focus on HRA Approval and Transparency. The group noted similar events are planned in Wales and Northern Ireland.	
9.	**DH update** Legislation to establish the HRA as a NDPB The group noted this work was going to plan with the Commencement Order, which gives effect to clauses in the Care Act, made on 12th September confirming that the establishment will take place on 1 January 2015. The transfer order will follow in the near future. Recruitment to new HRA Board The group noted the advert for Non-Executive Directors to apply to join the new HRA Board upon it being established as a NDPB would be released shortly with interviews to take place early in November. Public Accounts Committee BD advised a follow up hearing to include Tamiflu and transparency regarding research results will begin in the near future. It is likely the progress made by the HRA will feature in the hearing.	
10.	**Update from Northern Ireland** Director of R & D JB advised the new Director of R & D had yet to be appointed. R & D Strategy JB advised this had not been issued for consultation as yet. Revision of data protection legislation JB advised the consultation on the proposal to introduce primary legislation for the use of health and social care service user identifiable information for secondary purposes in controlled circumstances was due to close on 10 October 2014. Association of British Pharmaceutical Industry (ABPI) joint event JB advised a successful joint event with the ABPI was held last week involving 19 client companies to consider Northern Ireland as a place to conduct clinical trials.	
11.	**Update from Scotland** Chief Scientist Office Health Research Strategy The group noted the consultation was due to close shortly.	

	Chief Scientist Office (CSO) and HRA workshop in Edinburgh MS advised the event had been a success with a general conclusion made that the Scottish and English systems could work well together and agreement for the event to be repeated.	
12.	**Update from Wales** National Institute for Social Care and Health Research (NISCHR) infrastructure LD advised the infrastructure work was ongoing with an idea of the likely structure from April 2015 anticipated mid-November 2014. LD advised the launch of the new infrastructure would take place on 14th May in Cardiff. Performance management meetings The group noted meetings with NHS organisations in Wales would take place in the near further with a RAG style report to be piloted to assess whether each organisation is meeting relevant targets.	
13.	**R & D Compatibility Group update** Amendments The group noted the cross border amendment process was still being finalised. Study wide review of non-portfolio studies The group noted a mechanism for NHS organisations to provide feedback on the structure of the assurance template will be available on the HRA website from November 2014.	
14.	**UK wide arrangements for IRAS and HARP** JM advised the HRA was in the process of reviewing the structures for internal systems with a new HARP management board and IRAS management board created to provide assurance for the two systems. JM queried how the DAs would like to be kept informed and what representation they would like on the available boards. This would involve consideration from a REC perspective and also in terms of engaging with new integrated ways of working. The group noted HARP was a potential solution for the electronic submission of documents and this would need to be compatible with individual systems in the DAs. JM advised of a long term ambition to potentially use HARP as a system which would record all processes around assessment as well as REC review. The group noted there were questions surrounding how this could be made visible to R & D. The DAs advised it would be helpful to receive clarity on how the system will operate in England to allow any decisions to be made. The group noted the importance of understanding the DA requirements and timing. The group noted the need for compatibility with the European Clinical Trials Regulations requirements. The group noted clinical researchers in Europe will need to submit via the EU portal. The group noted IRAS could therefore potentially	

	become a system solely for the management of non CTIMP studies. The group agreed however that there is uncertainty regarding how the EU portal will operate and other complexities surrounding other approvals to consider. The group discussed providing R & D with access to HARP. The group agreed this would be helpful with regard to version control and having one documentation set. The group queried if there was a forum for how other systems, such as ReDA and EDGE, will interface with HARP and IRAS. JM was unaware of an established forum and the group agreed it would be useful to have a high level overview of the relevant systems including local trust level systems. JM agreed to conduct a mapping exercise of the relevant systems. ***Action: JM to conduct mapping exercise of systems*** JM agreed to set up a meeting with the relevant leads from the Clinical Research Network (CRN) and use links they have already established with EDGE. ***Action: JM to set up meeting with EDGE via CRN*** The group agreed whatever system is put in place will need to take amendment working into account. The group agreed it made sense to establish the initial system first and understand the issues with R & D before adding amendments to the system. The DAs agreed it was too early to consider the DA representative on the HARP and IRAS management Boards and agreed to consider once further clarity has been provided.	**JM** **JM**
15.	**Any other business** <u>Central Booking System (CBS)</u> LD flagged the number of studies booked via the CBS had decreased recently with researchers being advised that there were no meeting slots available, however locally it showed there were slots available. Also, certain studies had been booked as proportionate review studies instead of full studies and vice versa. The group noted this had an impact on the management information and should be addressed. ***Action: JW agreed to speak to Joan Kirkbride regarding the CBS*** <u>Update to HARP software</u> LD advised the recent update to the HARP software had been incompatible with the system in Wales. The group noted this issue was being addressed however in the meantime staff had to use workarounds to do their work.	**JW**
16.	**Date of next meeting** 18 November 2014, 1pm – 3pm, HRA 1 / teleconference	