FOUR NATIONS' MEETING
MINUTES

Minutes of the Four Nations' Meeting, held on Tuesday 21 January 2014 from 11.30am – 2.00pm in HRA Room 2, Skipton House, 80 London Road, London, SE1 6LH

Present		Initials
Janice Bailie, Health and Social Care Research & Development		JB
Simone Bayes, Department of Health		SB
Louise Dunstan, National Institute for Social Care and Health Research, Welsh Government		LD
Amanda Hunn, Health Research Authority		AH
Janet Messer, Health Research Authority		JM
Alex Newberry, National Institute for Social Care and Health Research, Welsh Government		AN
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** None to note	
2.	**Minutes of previous meeting held on 02 October 2013** The group agreed the minutes of the previous meeting were an accurate representation of the matters discussed without amendment.	
3.	**Matters arising** None to note	
4.	**UKECA Business** <u>Reconfiguration of HSC RECs at ORENCI</u> UKECA noted the previous HSC RECs 1, 2 and 3 are due to be merged into HSC RECs A and B. UKECA formally recognised the RECs to review CTIMPs in healthy volunteers (Type 1) and CTIMPs in patients (Type 3). UKECA noted both RECs would be flagged to review medical devices, research involving children, persons with mental incapacity and prisoners. UKECA noted HSC REC A would be flagged to review Research Tissue Bank studies and HSC REC B would be flagged to review Research Databases. <u>North of Scotland REC 1</u> UKECA agreed with the proposal for the removal of the recognition status for North of Scotland REC 1 from 1st February.	
5.	**HRA Collaboration and Development Programme update**	

	Sponsor responsibilities consultation The group noted the consultation was taking place within England only however issues from the consultation would feedback into this group. MS advised the sponsor responsibilities issue was discussed at the NRS Board last week where it was agreed the list of issues identified do sometimes occur in Scotland. The Board however was uncertain if the issues occurred because of the quality of the sponsorship and not because of other governance issues. AN advised Wales would consider this in March and JB advised Northern Ireland would consider in February. The group noted the consultation is due to close at the end of February and a further discussion will take place at the next meeting. ***Action: ST to add to next agenda*** RGF The group noted a number of the projects previously governed through the C & D programme now sit better under the Research Governance Framework Steering Group (RGF SG) and have been transferred.	**ST**
6.	**Research Governance Framework update** The group noted the first RGF SG meeting had been held. The RGF SG had agreed for a reflection period to take place for each country before any reports are circulated for wider comment. The RGF SG aimed to have a document ready for consultation upon the HRA becoming an NDPB. AH gave an update on project 1 – how to support research in the NHS. The group noted an independent working group was supporting this project and its independent view would be published, which the HRA would comment on. The group noted the project initially considered own account and educational research however AH advised no real quality issues with own account research had been identified and the proportion of own account studies had decreased therefore the main focus of the project related to student studies. The group noted the working group was due to meet on 5th February with a paper to be circulated to the DAs in February for reflection before the comment period begins on 17th March.	
7.	**HRA update** EU Clinical Trial Regulations The group noted an agreement had been reached in December 2013 on the European Clinical Trials Regulation which will replace the current European Clinical Trials Directive. It is anticipated the regulation will apply from mid-2016. The group noted Sue Bourne had prepared a detailed update document on the regulations which would be available on the HRA website in the near future. The group noted the regulations will introduce a simplified application process which will be dependent on an EU portal being developed. Transparency The group noted a number of organisations had requested a postponement to the trial registration requirement due to commercial sensitivities. These all relate to	

	phase 1 studies and the HRA has accepted the postponement until after phase 2 has commenced. The HRA will consult with the devices industry with an intention of bringing the requirements for devices studies in line with other clinical trials by March 2014. The group noted when the clinical trial regulations come into force all clinical trials in the EU will need to be registered and a summary of results be published within one year of the trial ending. <u>Publication</u> A workshop is scheduled to take place in March to consider what publication means for different audiences, what are the practical barriers to publication and how can the HRA obtain an overall publication picture for the UK. <u>Ethics Officer evaluation</u> The group noted the results showed the work conducted by the ethics officers had not been statistically significant in reducing the number of provisional opinions by increasing the number of favourable opinions; however the feedback received from researchers had been extremely positive. The group noted the analysis had shown that the work conducted by the officers had looked at more administrative issues than actual ethical issues. A next stage for the evaluation is being developed however the group noted this would look quite different to the original pilot. <u>Proportionate Information for Proportionate Review Pilot</u> The group noted initial analysis showed that proportionate review sub-committees had been able to make decisions using reduced data sets. The next step of this work will be to look at live testing for RECs and potentially dummy testing with R & D. <u>CAG</u> The group noted Rebecca Stanbrook's secondment with the HRA had finished and the management of CAG would now sit under the HRA operations directorate whilst the decisions relating to advice would remain with JW, delegated to Stephen Robinson. <u>HARP</u> The group noted the HARP development was progressing well.	
8.	**Department of Health update** <u>NHS England</u> The group noted the NHS England R & D strategy had been published for consultation and was open until next week. <u>Regenerative Medicine Expert Group</u> The group noted this group had been established with Sir Michael Rawlins as the chair. A regenerative medicine strategy is anticipated to be developed by December 2014. <u>ACAT template</u> The Activity Capture and Attribution Template (ACAT) has been developed to support researchers apply the AcoRD (Attributing the costs of health and social	

	care Research and Development) guidance published by Department of Health (DH) to identify fully and attribute correctly the activities being undertaken as part of a research study.	
9.	**Update from Northern Ireland** Health and Social Care Strategy The group noted the strategy was extended to the end of 2013 and it may be extended further until the end of the financial year. Atlantic Philanthropies JB advised partnership funding with Atlantic Philanthropies had been established with work to take place on a variety of topics, such as dementia.	
10.	**Update from Scotland** Research strategy The group noted a revised research strategy was being prepared and would go out for consultation in the near future. Team structure MS advised he was looking at restructuring the team following Craig Gilbert's departure. GCP training course The group noted Scotland had recently agreed to adopt a common GCP training course across the country. Care Bill MS advised the legislative competence motion had been made in parliament last week.	
11.	**Update from Wales** Update to REC names LD advised the names of the RECs in Wales were no longer very reflective and would be renamed from 1 to 7 from 01 April 2014. Update to job titles LD advised the job titles would be changed from 1st April to match with the new job titles in England e.g. REC coordinators now named REC managers. R & D office review LD advised an event was due to be held in March to consider methods to optimise the way R & D offices are run. Restructuring of the NISCHR funded infrastructure and programmes The group noted this was currently out for consultation with a proposals document to follow shortly.	
12.	**R & D Compatibility Group update**	

	Amendment work The group noted work was continuing to allow people to become used to the new systems. AN flagged there was the potential for a delay to the go-live date due to difficulties with scheduling the subsequent meeting date for the group.	
13.	**Any other business** Responsibilities in the HRA The group agreed it would be useful to set out for the Devolved Administrations what areas of business people are responsible for in the HRA. ***Action: ST agreed to draft a document detailing what each Director is responsible for and share with colleagues at the next meeting***	**ST**
14.	**Date of next meeting** Tuesday 18 March 2014, 1pm – 4pm	