FOUR NATIONS MEETING
MINUTES

Minutes of the Four Nations Meeting, held on Tuesday 26 January 2016 from 1.00pm – 4.00pm in HRA 1, Skipton House or via teleconference

Present		Initials
Janice Bailie, Health and Social Care Research & Development		JB
Graeme Campbell, Chief Scientist Office		GC
Richard Carter, Department of Health	*(in part – items 1-5)*	RC
Sue Cartwright, Department of Health		SC
Bill Davidson, Health Research Authority	*(in part – items 6-8)*	BD
Louise Dunstan, Division for Social Care and Health Research		LD
Katherine Guerin, Health Research Authority		KG
Janet Messer, Health Research Authority		JM
Alex Newberry, Division for Social Care and Health Research		AN
Joanne Rodger, Chief Scientist Office		JR
Mike Stevens, Chief Scientist Office		MS
Stephen Tebbutt, Health Research Authority		ST
Janet Wisely, Health Research Authority		JW

Item	Item details	Action
1.	**Apologies** None to note	
2.	**Minutes of the previous meeting** The group agreed the minutes of the previous meeting were an accurate representation of the matters discussed without amendment.	
3.	**Matters arising** <u>Guidance on information for participants at the end of a study</u> The group noted Amanda Hunn was in the middle of revising the guidance based on the feedback received over the first six month period of use, plus the feedback received from Wales. The group noted a revised draft will be brought to the Four Nations group for comment and further revision with the aim of achieving a UK wide document. <u>European Clinical Trials Regulation – update on expected date of application</u> In October 2015, the EMA published their anticipated timelines for the development of the IT infrastructure and thus the expected date of application of the Regulation (December 2017). Following a discussion at the EMA's Management Board in December 2015 the previously announced timelines have been revised and new dates published. The new timeline anticipates that: - The EU Portal and EU Database will be available for independent audit by	

	August 2017; - The European Commission will publish the notice in OJEU in March 2018 (assuming that the independent audit confirms that EU Portal and EU Database are full functional); - The Regulation will become applicable by October 2018 It should be noted that in publishing these revised timelines, the EMA have stated "this is the maximum timeframe and every effort will be made to shorten it and bring the Regulation into operation as soon as possible."	
4.	**UKECA Business** <u>UKCTG and endorsement / approval of registries</u> UKECA noted the establishment of patient registries is not an activity that requires research ethics committee approval however future recruitment would require REC review on a project basis. JW highlighted the UKCTG proposals for the creation of a registry and UKECA noted a panel has been set up in England by the HRA, consisting of members from RECs and CAG, to undertake an advisory review in the first instance, with Mark Taylor, CAG Chair, chairing the group. The HRA expected to be asked to then endorse the registry. It was noted that in other countries they had simply approved using a REC – to achieve the same purpose as assurance to the relevant REC when reviewing a specific application which used the registry as a recruitment method. The other countries did not see the endorsement model applicable in the same way as for England and the HRA. JW suggested that there may be a simple solution that if the HRA in endorsing / approving always convened a group that mirrored REC membership quorum requirements (which was the intention) there could be mutual recognition of either a panel approval in England or REC in the other countries. Noting for the HRA because it also responsible for CAG it wanted to include that dimension as well as REC. UKECA agreed to consider at a future meeting the principles regarding the endorsement of registries. ***Action: ST to add registries to future meeting agenda***	**ST**
	<u>Domestic provisions regarding RECs under the new EU Clinical Trials Regulation for information</u> UKECA noted the updated provisions. MS queried if there was a definition for 'Appropriate Authorities' and noted clause 5 does not seem to deal with the Adults with Incapacity (AWI) REC. BD agreed to seek clarification from Anne Paskin, Senior Lawyer, MHRA, Nutrition and EU Team, DH Legal Advisers.. ***Action: BD to seek clarification from Anne re appointing authorities and AWI query***	**BD**
5.	**HRA Approval: SSI / local information provision to research site considerations** UKECA noted the summary of responses, circulated prior to the meeting which had been received in each country, with 5 received from Wales, 14 from Scotland, 7 from Northern Ireland and 60 from England. UKECA agreed to consider the requirements for commercial and non-commercial studies separately.	

	Non-commercial UKECA recognised the need for some kind of site specific information and agreed to work collectively towards a revised information set. In the meantime the HRA would continue to test an alternative option, through the Statement of Activity and Schedule of Events with other countries to continue to use SSIs. UKECA agreed the messaging should advise the UK is working collectively towards a new kind of site specific information; SSI forms were required for Scotland, Wales and Northern Ireland whilst in England SSI forms were not required with the HRA to continue to test an alternative in the interim period. JW noted that feedback was that it was quite challenging for some to complete the new formats being developed by HRA, and that cohort 3 studies in this interim may see the England approach more challenging than continuing to complete (potentially not fully) an SSI form. UKECA discussed the format of the new site specific information and agreed a two part pack would be beneficial. Part A could contain the information required from the sponsor to be submitted to the site and would be what needs to be provided UK wide. Part B would contain the further information required for the site and the timing of when and how that was provided could be nation specific. UKECA agreed a discussion regarding what is required should be held asap to allow the UK wide position to be agreed. UKECA agreed to explore to have a new site specific information approach by March 2016. UKECA recognised the changes will require an update to IRAS which realistically would take longer to finalise however noted the current SSI Forms created from Part C could be disabled on IRAS. UKECA agreed a link to a form could be provided instead from 01 April 2016 with combined UK wide messaging to advise that the site specific information is being revised UK wide with a new document to be available on IRAS in due course. *Commercial* UKECA noted the positive feedback from industry regarding the possibility of no longer requiring a SSI form. UKECA agreed to explore having a new site specific information approach by March 2016. HRA concluded that UKECA agreed (subsequently not accepted as agreement by all parties at 22/03/2016 meeting), for commercial studies, the SSI form was not required with a new simple log of who does what to be developed by end March as an alternative. UKECA agreed by March the relevant sections of IRAS should be switched off with a template to be downloadable from IRAS whilst the development work takes place. UKECA delegated the detail to operational colleagues to ensure the new process is in place from 1st April. UKECA agreed it would be helpful to invite Clare Morgan from the NIHR CRN to this workshop. UKECA agreed to encourage the submission of studies meeting the definition of cohort 3 or cohort 4, including those with cross-border sites as part of the roll-out and testing through to end of March.	

6.	**Transfer of GAfREC from DH to HRA** The group agreed with the recommended option for the HRA to publish GAfREC as soon as possible with minor updates to branding / references and addition of arrangements for REC review of research involving DNA from acellular tissue. Wales flagged their upcoming election and BD agreed to turnaround in the next 4 – 6 weeks.	
7.	**HRA Collaboration & Development Programme update** <u>Model Clinical Trial Agreement (mCTA)</u> The group agreed for Alastair Nicholson to lead the discussions with the ABPI for a revised draft of the mCTA, with other leads in the DAs to support as required, diaries permitting. The group noted BD was in meetings with the same people and may be able to reinforce some of the messaging. <u>Model Non-Commercial agreement (mNCA)</u> JM advised Alastair was in the process of collating the feedback from the meeting before Christmas in order to create a version for legal review and sharing with the DAs. <u>Technical assurances</u> JM advised the report for the radiation technical assurance work is being finalised and would be reviewed by the Executive Management Team next week. ***Action: JM to share radiation technical assurance report with DAs***	**JM**
8.	**Update on UK Policy Framework for Health and Social Care Research consultation** The group noted the update. The DAs flagged some responses may be received directly by each nation.	
9.	**Expired accreditation status Wales 4 REC** The group noted the expired accreditation status for Wales 4 REC and the subsequent action plan to address the non-compliance issues identified as part of the audit process.	
10.	**Update from HRA** None to note.	
11.	**Update from Department of Health** <u>Chief Scientific Adviser</u> The group noted Professor Chris Whitty has been appointed as the Chief Scientific Adviser with the Research and Development Portfolio for DH. <u>Permanent Secretary at the Department of Health</u> The group noted Chris Wormald had been announced as the new Permanent Secretary for DH following Dame Una O'Brien's recent announcement to step down from the role.	

	DH 2020 Plans RC advised an announcement is anticipated in the near future regarding DH's 2020 plans.	
12.	**Update from Northern Ireland** R & D Strategy JB advised the strategy is due to be released on 11th February 2016. JB advised planning has started for various workstreams with an implementation plan to be developed and an infrastructure review to take place.	
13.	**Update from Scotland** Graeme Campbell The group welcomed GC back from his secondment. 2020 Workforce Vision MS advised the plan would be implemented from April 2016.	
14.	**Update from Wales** Work to enhance NHS Approvals AN advised this covered a wide range of projects with the first meeting to take place on Thursday. Operational strategy AN advised the strategy was currently out for comment regarding the national workforce review. HealthWise Wales AN advised the cohort registry was due to be launched on 29th February.	
15.	**UKREDG update** Operational Updates under consideration by UKREDG – Briefing for UKECA The group noted the action and information log should be updated with ST to liaise with Charlotte Allen to feedback the group's decisions. *REC letter templates* – The group noted it had agreed the letters should be issued on headed paper however the log did not capture this decision and asked ST to confirm. ***Action: ST to double check outcome of REC letter templates action*** *Chair's Appraisal programme* – the group was interested in this being a UK wide programme. Version number of documents The group noted the operational group had held discussions around REC letters and the version numbers of documents listed within the letter. JB advised she had raised with Siobhan McGrath to take to UKREDG for a UK wide discussion. ST	**ST**

	agreed to follow up. ***Action: ST to confirm UKREDG discussion regarding version number of documents***	**ST**
	<u>HRA statement regarding GCP training – issued noted at UKREDG</u> ST advised conversations had been held at previous UKREDG meetings where it appeared GCP training is being requested by some RECs for all studies and not just CTIMPs which is inconsistent with the statement issued by HRA and supported by DAs regarding researcher training being appropriate and proportionate. The group reconfirmed it was supportive of the HRA statement with training being proportionate and agreed to feedback to operational colleagues to ensure the principles of proportionality are applied by RECs. ***Action: All to feedback to operational colleagues re proportionality of GCP training***	**ALL**
16.	**Any other business** None to note	
17.	**Subsequent additional meeting held on 04/02/2016** A subsequent additional meeting was held on 4th February 2016 to further the discussions regarding the use of a combined REC and R & D form and E-submissions. The following individuals were present: Janice Bailie, Health and Social Care Research & Development Graeme Campbell, Chief Scientist Office Richard Carter, Department of Health Bill Davidson, Health Research Authority Janet Messer, Health Research Authority Alex Newberry, Division for Social Care and Health Research Joanne Rodger, Chief Scientist Office Mike Stevens, Chief Scientist Office Stephen Tebbutt, Health Research Authority Janet Wisely, Health Research Authority UKECA noted the paper circulated by JW on 30th January 2016 setting out the following policy position: - Agreement to adopt UK wide from end March 2016 and this has been communicated - In reaching this agreement, UKECA noted this combined two long forms (ethics and R&D) to one slightly longer form - Concerns were raised that this would result in 'mission creep' if REC members reviewed the new information that would become visible to them. UKECA agreed this could be managed through training - Concerns were raised that this would result in changes to REC SOPs, England reassured colleagues that the REC validation would remain as first point after submission - The HRA is though setting out an expectation that the combined form when it is submitted is complete in its entirety to meet REC validation and	

	the subsequent initial assessment. UKECA confirmed UK wide agreement in having a combined REC and R & D form to support the changing of behaviours of researchers to consider the whole research process at an earlier stage. UKECA discussed the concerns regarding the practicalities of the adoption of a combined form. UKECA noted the current situation of researchers obtaining REC approval to meet funding requirements, and subsequently submitting amendments as with funding they develop the protocol and prepare to apply for NHS permission. MS noted there may be situations when a separate REC form may be required. JW advised in England the expectation would be for a combined form to be submitted however if a researcher requested to proceed on a REC only basis a conversation would be held to discuss further. There wouldn't be a direct route, but it would be an option available but not one the HRA would encourage. There would be the REC form for non-NHS applications. UKECA agreed the validation of a REC & R & D combined form was not the issue; it is the associated documentation which posed an issue. In practical terms there may be documents required for R & D purposes which are not ready when REC submission takes place. UKECA agreed the relevant documents could be submitted at a later date if that was the preference in other countries. UKECA noted the issue of overwriting if e-submission occurs once for REC purposes and then subsequently for R & D purposes and problems that would cause with document control. To resolve this UKECA agreed the later documents could be submitted via email as this would not overwrite the information. UKECA discussed how likely it would be for information to be changed between REC submission and R & D submission. UKECA noted the list of documents, which Mary Cubitt had submitted via MS Excel spreadsheet prior to the meeting, which are additional for R & D and not required for RECs. UKECA agreed it needed to define the documents which could be submitted at a later stage with the practicalities regarding their later submission to be considered. UKECA discussed the practicalities of single site study submissions. JW highlighted single site studies, in cohort 5, would still go through HRA Approval but with a lighter touch. UKECA noted the handling for single centre studies differed between the DAs. In Scotland and NI single site studies were not managed through the coordinating centres and there was not capacity to do so and e-submission of single site studies via the coordinating centres was not therefore an option they could consider. This meant more consideration was required of the specification required to allow e-submission to take place. The DAs agreed e-submission should be delayed to allow the solutions to be identified to allow all 3 countries to proceed at the same time. Noting though that because Wales used the coordinating centre as a post box it had been able to submit detailed comments on the specification produced by the HRA for the DA, and could have progressed using adaption of the Approval functionality. UKECA agreed to delegate the technical solution to manage the complexities to operational colleagues with the e-submission date to be later than the scheduled 1st April 2016 go live date. UKECA continued discussions regarding site specific information requirements from the meeting last week *(item 5)* and noted the SSI form was not being	

	requested in England for cohorts 3 and 4 ahead of 1st April. UKECA noted this resulted in a difference between the forms required between England and the DAs however JW flagged this was a period of transition and it was important for an appropriate alternative to be tested without adding an additional burden on researchers during this testing phase. UKECA noted the SSI form was still being used in the DAs. MS asked if JW was aware if Industry had raised concerns that England had moved from the UK position, JW said she had not and would not have expected concerns to be raised when it was understood this was a testing period in England and that with the final switch over at the end of March for cohort 4 the intention was to settle on a UK position. JW added she felt it untenable for the HRA to ask for an SSI form from those agreeing to come through early as test studies, when it was now agreed and communicated that at the end of March there would be a new reduced requirement for site information. And the HRA had no use for the SSI form in the interim. The DAs expressed concern with the SSI form not being requested. MS agreed to write formally, on behalf of the DAs, to Richard Carter at DH expressing these concerns. UKECA noted the date for the workshop to consider the operational practicalities was hoped to take place on 16th February. Alex Newberry was leading on arrangements.	
18.	**Date of next meeting** 22 March 2016	