# FOUR NATIONS MEETING
# MINUTES

## Minutes of the Four Nations Meeting, held on Tuesday 02 June 2015 from 1.00pm – 3.30pm in HRA 3, Skipton House / via teleconference

| Present | | Initials |
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| Janice Bailie, Health and Social Care Research & Development<br>Catherine Blewett, Health Research Authority *(in part item 4 only)*<br>Claire Bond, National Institute for Social Care and Health Research<br>Janet Messer, Health Research Authority *(in part items 1-6)*<br>Alex Newberry, National Institute for Social Care and Health Research *(in part items 1-4)*<br>Joanne Rodger, Chief Scientist Office<br>Mike Stevens, Chief Scientist Office<br>Stephen Tebbutt, Health Research Authority<br>Janet Wisely, Health Research Authority | | **JB**<br>**CBl**<br>**CBo**<br>**JM**<br>**AN**<br>**JR**<br>**MS**<br>**ST**<br>**JW** |
| **Item** | **Item details** | **Action** |
| **1.** | **Apologies**<br><br>Sue Cartwright, Department of Health<br>Louise Dunstan, National Institute for Social Care and Health Research | |
| **2.** | **Minutes**<br><br>The group agreed the minutes of the previous meeting were an accurate representation of the matters discussed with the following amendments:<br><br>- <u>HRA Update, page 5, paragraph 2</u><br>The DAs expressed concern regarding the removal of SSI without any replacement and felt it should have been considered at a Four Nations meeting prior to release.<br><br>- <u>Update from Scotland, page 6, paragraph 1</u><br>MS advised a teleconference with the Medicines and Healthcare Products Regulatory Agency (MHRA) had been held to discuss widening the definition of sites for CTIMPs. MS advised a process was being worked up with the MHRA and would be brought to a future Four Nations meeting for consideration in other countries. A hypothetical example of the need for the process was described as follows: A patient in Inverness unable to participate in a cancer trial in Glasgow and the need to make alternate arrangements for scans available, e.g. off site. | |
| **3.** | **Matters arising**<br><br><u>Pharmacy and Radiation assurance workshops</u><br>JM advised further workshops are being planned.<br>***Action: JM agreed to confirm the representation of DA participants at previous*** | **JM** |

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| | ***workshops and confirm future workshop arrangements.*** | |
| | <u>Post authorisation safety studies</u><br>The group noted Sue Bourne had spoken with JR regarding this issue. The group agreed a decision on whether these studies were research should be made on the class of study as a whole rather than each individual study. The group agreed it would be helpful to have an update from Sue at the next meeting.<br>***Action: ST to invite Sue Bourne to next meeting*** | **ST** |
| | <u>Training</u><br>The group noted the REC member induction module had been launched with excellent feedback received. | |
| | <u>UK wide slides / EU Clinical Trial regulations</u><br>JW confirmed a slide set had been received from Wales with UK wide considerations being carefully considered in recent presentations. The group noted there was some uncertainty amongst stakeholders regarding the timing of the implementation of the EU Clinical Trial regulations and noted the date was presented as May 2016 on MHRA slides. The group agreed consideration of messaging is important and agreed for Sue Bourne to discuss with Martyn Ward from MHRA. | |
| **4.** | **UKECA items**<br><br><u>UK Workload data</u><br>UKECA noted the information provided. ST clarified applications where Question 3 on the IRAS filter page *(In which countries of the UK will the research sites be located?)* had not been completed had not been included in this analysis. This equated to approximately 9% of studies. MS queried the variation between countries for studies which were reviewed by a REC in the country from which the research originated from *(England 67%, Wales 95%, Scotland 83%, Northern Ireland 95%)*.<br>***Action: CBl agreed to consider possible reasons for the variation and advise*** | **CBl** |
| | UKECA noted the figures for average number of applications per meeting was relatively low. UKECA queried if the number of RECs was set at the correct level however the group agreed RECs also reviewed proportionate review applications which needed to be taken into account. AN highlighted that Wales is currently beginning some work to consider further improving and simplifying NHS research approvals processes in Wales. AN agreed to provide an update at the next meeting.<br>***Action: AN to provide update at next meeting*** | **AN** |
| | UKECA noted RECs should be reviewing 5-6 applications per meeting with those RECs recognised by UKECA to review CTIMPs to review a minimum of 10 per year to maintain expertise. UKECA agreed operational colleagues should be asked to review the workload for recognised RECs and confirm they were meeting the requirement of 10 per year.<br>***Action: All to inform Operational colleagues to review workload figures*** | **ALL** |
| | <u>Publication of summary of REC opinion</u> | |

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| | UKECA noted this item had been raised at the last UKREDG meeting. UKECA noted the requirements of the *Medicines for Human Use (Clinical Trials) Regulations 2004* and *GAfREC: a harmonised edition* for RECs to publish a summary of the opinion. UKECA noted the number of requests for a full summary of opinion was relatively low and the work to produce a summary of opinion was an intensive and time consuming process. UKECA agreed the summary of opinion as so far as whether a study received a favourable or unfavourable opinion was currently published and UKECA was meeting its minimum requirement under GAfREC. UKECA agreed a full summary, in lay friendly language, should be provided and published when a request is received and the number of requests should continue to be monitored with UKECA to revisit this decision if the number of requests increased. UKECA agreed GAfREC will require a review in the medium term once the replacement to the Research Governance Framework, the UK policy framework for Health and Social care research, is published and the issue should be reconsidered then. | |
| **5.** | **HRA Collaboration & Development Programme update**<br><br>The group noted a thorough discussion had been held this morning to consider further the implications of HRA Approval on a UK wide basis. The group noted cohort 1 had gone live on 11th May with the first study having now been approved. | |
| **6.** | **Agreements between Devolved Administrations and HRA**<br><br>The group noted discussions had taken place outside of the meeting to consider any necessary changes to the agreements. The group agreed relatively few changes were required. The group noted the revised Welsh agreement had been circulated with the agenda and agreed the proposed changes were acceptable. CBo confirmed the Welsh agreement had been forwarded to the Minister for approval on Friday. | |
| **7.** | **NREAP and the DAs**<br><br>The group noted, as part of the discussions regarding DA finance recharges, an area raised for discussion related to the access to the National Research Ethics Advisors Panel (NREAP). The benefits of the NREAP to the DAs have been presented as including updating guidance, clarifying complex queries (UK wide impact), hosting of Chairs meetings and access to the panel for any queries. The group agreed to consider what the NREAP might be able to offer and bring back to the next meeting. ST agreed to invite Clive Collett to the next meeting.<br>***Action: DAs to consider what they would like to receive from the NREAP***<br>***Action: ST to invite Clive Collett to next meeting*** | **DAs**<br>**ST** |
| **8.** | **HRA update**<br><br><u>Judicial Review</u><br>The group noted the HRA's defence in relation to the judicial review was currently being prepared.<br><br><u>Guidance on lay summaries</u><br>The group noted the HRA has agreed to lead the work to consider the EU Clinical Trial regulation to provide a lay summary to participants at the end of a study. The | |

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| | group noted Amanda Hunn was leading this piece of work for the HRA and is in the process of setting up a European wide task force. The group noted Amanda had asked if a member of the group would be interested in joining the task force.<br>***Action: DAs to consider nominations to join task force*** | **DAs** |
| **9.** | **Department of Health update**<br><br>None to note. | |
| **10.** | **Update from Northern Ireland**<br><br><u>Director of R & D post</u><br>JB advised a decision had not been made as yet.<br><br><u>R & D Strategy</u><br>JB advised the strategy was currently with the Department.<br><br><u>New Health Minister</u><br>JB advised Simon Hamilton MLA had been appointed as the new Health Minister.<br><br><u>100,000 Genomes project</u><br>JB advised work was ongoing with regard to developing a bid to develop a genomic medicine centre and participate in the 100,000 genomes project. | |
| **11.** | **Update from Scotland**<br><br><u>Health Research Strategy</u><br>MS advised the strategy would be considered at the Health Management Board on 7th July with publication to follow later in the summer.<br><br><u>Engagement with REC Community</u><br>MS advised consideration had taken place regarding further engagement with the REC community. An annual meeting with REC Chairs and the CSO had been suggested which had been positively received by Chairs. | |
| **12.** | **Update from Wales**<br><br><u>NISCHR Conference</u><br>CBo advised the conference had taken place on 14th May to launch the new infrastructure and gave thanks to JM for attending.<br><br><u>NHS Approvals</u><br>CBo advised that the Health and Care Research Wales Support Centre is being commissioned to look at further improving and simplifying NHS approvals processes taking account of HRA assessment and approvals and the first meeting is due to take place on 4th June. | |
| **13.** | **UKREDG update**<br><br><u>UKREDG membership</u><br>ST confirmed UKREDG had accepted UKECA's proposal for the revision to the | |

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| | membership.<br><br><u>Removal of NRES brand</u><br>ST advised the NRES brand was being removed from documentation. UKREDG had requested advice from the Four Nations regarding how ethics committee should be referred to UK wide. The Four Nations agreed with the current wording of *UK Health Departments' Research Ethics Service*. | |
| **14.** | **Any other business**<br><br><u>Indemnification for pharmacy and radiation assurance reviewers</u><br>The group noted pharmacy and radiation assurance reviewers were covered by an agreement from the NHS Litigation Authority. ST raised the issue of arrangements for cross border studies. The group noted each other's reviews are currently accepted for R & D purposes without any specific cross border cover being agreed. The group agreed it would be helpful to have an item on indemnity and audit on the next agenda.<br>***Action: ST to add to agenda*** | **ST** |
| **15.** | **Date of next meeting**<br><br>28 July 2015, 1pm – 4pm | |