

## FOUR NATIONS MEETING MINUTES

**Minutes of the Four Nations Meeting, held on Tuesday 27<sup>th</sup> September 2016  
from 10.00am – 1.00pm in Conference Room E, St. Andrew's House and via  
teleconference**

Present		Initials
Teresa Allen	Health Research Authority	TA
Janice Bailie	Health and Social Care Research & Development	JB
Sue Cartwright	Department of Health	SC
Amanda Hunn	Health Research Authority	AH
Janet Messer	Health Research Authority	JM
Alex Newberry	Research and Development Division	AN
Joanne Rodger	Chief Scientist Office	JR
Stephen Tebbutt	Health Research Authority	ST
Ricky Verrall	Chief Scientist Office	RV
Gordon Watt	Chief Scientist Office	GW
Item	Item details	Action
1.	<b>Apologies</b>  Janet Wisely, Health Research Authority	
2.	<b>Minutes of the previous meeting</b>  The group agreed the minutes of the previous meeting were an accurate representation of the matters discussed without amendment.	
3.	<b>Matters arising</b>  <u>Model Non-Commercial Agreement</u> The group noted an update would follow at for the next meeting.	
4.	<b>Rationale for the use of a combined REC &amp; study-wide submission</b>  JM presented a paper which provided DAs with the context and explanations for the HRA decision to implement a combined REC and study-wide submission. The DAs advised they had consulted their communities regarding the changes and there was general support from stakeholders. JB flagged one researcher had offered to be part of any pilot in Northern Ireland. The DAs agreed to the proposal of a combined REC & study-wide submission.  The group noted the number of actions and challenges detailed in the paper and queried how these were to be taken forward and addressed. The group discussed portal and access arrangements which will need to be resolved in the interim	

	before a full electronic interface can be developed with each nation's system.	
5.	<p><b>Development of a UK Local Information Template for Use in Research Approval Process</b></p> <p>The group noted the outcomes of the UK working group regarding a consistent approach to the provision and use of information to support NHS/HSC approval. AN advised the working group was close to a consensus on what a compromise solution would look like for the local information package. The group noted there were a few issues however still to be resolved and a further working group meeting would be required. The group flagged the need for the working group to consider the commercial versus non-commercial split and also the implication for metrics.</p> <p>The group discussed how this work could be taken forward and resourcing implications as it would require a change in culture in each country. The group agreed an individual was required to drive this forward however input would still be required from each country. The group agreed a 6 month, UK wide secondment was required, reporting to the Four Nations group, with project management skills and a good understanding of the associated issues. The group agreed payment for this role could potentially be built into the recharge for DAs. JM agreed to draft a job specification and consider the secondment process.</p> <p><b>Action: JM to draft job specification and consider the secondment process</b></p> <p>The group discussed the need to develop an action plan for IRAS development work factoring in the relevant business need. The group agreed the preference was for a single or minimal releases, rather than incremental changes, with relevant communications, guidance and training to be developed to provide support.</p>	JM
6.	<p><b>Amendment Proposals</b></p> <p>The group reviewed the table detailing the policy decisions required relating to improved amendment handling across the UK. The group reviewed each point in turn.</p> <ol style="list-style-type: none"> <li>1. <i>Lack of understanding from applicants of what needs to be submitted to REC and national coordinating functions as an amendment.</i></li> </ol> <p>The group accepted the recommendation to update the guidance with a communications plan to be developed and delivered. The group noted some of the work had already been done so it was not a huge task. The group accepted the supplementary recommendation that certain items do not need to be submitted as amendments and work is undertaken to take this forward. The group however was uncertain regarding who would undertake this work and noted there were some areas where there is variation between countries which will require agreement on.</p> <ol style="list-style-type: none"> <li>2. <i>Inefficiency across whole system caused by multiple amendments within a very short space of time</i></li> <li>3. <i>It has been observed that some REC staff are unbundling amendments that contain new site or new PI information to avoid having a REC unfavourable</i></li> </ol>	

	<p style="text-align: center;"><i>opinion of the whole amendment impacting new site set</i></p> <p>The group agreed clarification regarding multiple amendments should be led by R &amp; D with UKREDG to lead implementation in relation to RECs.</p> <p style="padding-left: 40px;">4. <i>Researchers confused by different formats of categorisation emails being sent from national coordinating functions</i></p> <p>The group accepted the principle of using a UK wide template.</p> <p style="padding-left: 40px;">5. <i>Lack of consistency in categorisation across the UK (long standing issue)</i></p> <p>The group agreed it would be helpful to hold a workshop on categorisation to agree appropriate methods to allow a training package to be delivered to those who undertake categorisation. The group queried who would lead this piece of work.</p> <p style="padding-left: 40px;">6. <i>Inefficiency in amendment submission processes and transparent audit trail for versions etc.</i></p> <p>The group discussed the various ways information is entered into the system and agreed with the intermediate step of e-submission from HARP into a portal to allow people to manually extract the relevant information and upload to DA IT systems until a direct link can be established with each system in turn. The group agreed this would allow immediate access and was an urgent step to progress as it will be key to other aspects of work.</p> <p style="padding-left: 40px;">7. <i>Mismatched timings between amendment submission to REC and national coordination functions.</i></p> <p>The group agreed with the proposals.</p> <p style="padding-left: 40px;">8. <i>Inconsistent start of 35 days to implement amendment across the UK</i></p> <p>The group agreed the start date should be the date of e-submission.</p> <p style="padding-left: 40px;">9. <i>Categorising amendments is resource heavy for national coordinating functions</i></p> <p>The group agreed in principle to explore this issue however agreed it was not a high priority with the training piece of work required first. The group noted the disparity in sponsor capability with some sponsors able to categorise amendments appropriately.</p> <p style="padding-left: 40px;">10. <i>There is a study wide review of new applications but not for amendments which means:</i></p> <ul style="list-style-type: none"> <li>- <i>Opportunities for efficient working are not maximised</i></li> <li>- <i>Inconsistent decisions/queries at site level</i></li> </ul> <p>The group agreed to this in principle however accepted it was not a priority at the current time and a further understanding of the benefit would be helpful.</p>	
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	<p>The group noted the resourcing implications for the progression of these proposals and agreed the 6 month secondment role may be in a position to undertake some of this work.</p>	
<b>7.</b>	<p><b>Operational Leads Topics</b></p> <p>The group reviewed the list of topics identified by the Operational Four Nations group and agreed a process mapping exercise considering business priorities and timing alongside technical implications would be helpful with an action plan / Gantt chart to be produced. The group agreed the Operational group should lead this work with the plan to come back to the Four Nations group for approval. The group however noted the Operational group was not, as yet, formally established and had been meeting on an ad-hoc basis. The group agreed terms of reference for the Operational Group should be drafted but in the meantime the Operational Group could begin to progress this work whilst the governance structures are formalised.</p> <p style="text-align: center;"><b>Action: ST to draft Operational Group ToR for Four Nations group review</b></p> <p>The group discussed the need for resource from within each country to take this work forward. The group agreed once the action plan has been developed resourcing implications and prioritisation could be considered, however noted the urgent need for some of the projects to begin.</p>	<b>ST</b>
<b>8.</b>	<p><b>UK REC SOPS review to enable greater flexibility for assignment within staff roles</b></p> <p>The group approved the proposal for a review to be undertaken to edit SOPs so that procedures are not assigned to particular staff roles and to identify potential opportunities for proportionality. The group agreed any changes would have minimal impact on researchers or RECs. The group noted the intention of a new version of SOPs to be drafted by December 2016 for UKECA approval.</p>	
<b>9.</b>	<p><b>New Model for Seeking Professional Expert Opinion: Proposal</b></p> <p>The group noted the paper from AH detailing a proposed new way of seeking professional expert opinion to replace the current National Research Ethics Advisors' Panel (NREAP). AH flagged the proposal was for a wider, virtual panel of people incorporating a greater range of expertise with relevant individuals to be called upon depending on the need.</p> <p>The DAs were supportive of the direction of travel in the proposed model however agreed the UK wide element required further clarification. The group noted the level of liaison with NREAP and the DAs had been limited over the years with NREAP hosted Chair's meeting scheduled but not as yet taken place. AH advised in the new model individuals from each country could be added to the membership list with DAs to consider any potential nominees, including REC Chairs.</p> <p style="text-align: center;"><b>Action: DAs to consider individuals to join the panel and notify AH</b></p>	<b>DAs</b>
<b>10.</b>	<p><b>Endorsement of registries in England and associated principles</b></p> <p>The group noted this paper sets out a proposal to establish a group to review and</p>	

	<p>endorse recruitment registries in England. The group noted the future possibility of a specific application form to support the endorsement of registries via IRAS however in the interim accepted the proposal to set up a panel in England to review and provide recommendation to the HRA for the endorsement of registries / recruitment databases.</p> <p>The group noted this panel would draw on draw on members from both existing RECs and CAG. The panel would be an advisory body and the HRA would reserve the right to not accept the recommendation of the panel.</p> <p>The group noted the importance of avoiding the perception that the wrong set of questions have been previously asked in the approval of registries which would undermine existing registries. AH advised the core principles contained within her paper underpinning the endorsement of registries would be shared with existing registries in order to protect public confidence.</p>	
<b>11.</b>	<p><b>Master Indemnity Agreements</b></p> <p>The group noted the Master Indemnity Agreements documentation has recently been revised by the DH however a number of the changes require further clarification as to how they are to be interpreted to avoid the possibility of different approaches being followed.</p>	
<b>12.</b>	<p><b>HRA Approval update</b></p> <p><u>HRA Approval Performance Report</u> The group noted the report circulated by JM. JM advised a smaller summary of information, relating to the cleared backlog, is due to be published shortly.</p>	
<b>13.</b>	<p><b>HRA Collaboration and Development update</b></p> <p><u>Phase 1 Trials on patients in the NHS</u> JM advised a workshop to consider potential differences between setting up and running phase 1 trials in the NHS and in private units was being planned. DAs agreed to notify JM of any relevant individuals to join this event. <b>Action: DAs to inform JM of relevant individuals</b></p>	<b>DAs</b>
<b>14.</b>	<p><b>HRA update</b></p> <p><u>Director of Finance</u> The group noted the HRA had appointed Karen Williams as its new Director of Finance. A start date had not as yet been confirmed.</p>	
<b>15.</b>	<p><b>Department of Health update</b></p> <p><u>Richard Carter</u> SC advised Richard is due to retire at the end of October.</p> <p><u>DH2020</u> SC advised the senior sponsor was not yet in post but this should be confirmed imminently.</p>	

<p><b>16.</b></p>	<p><b>Update from Northern Ireland</b></p> <p><u>Review of infrastructure</u>  JB advised the review of infrastructure was moving ahead with agreement in place to appoint someone to lead this work who would hopefully be recruited in the new year.</p>	
<p><b>17.</b></p>	<p><b>Update from Scotland</b></p> <p><u>Personnel</u>  RV confirmed he had been in post for approximately 4 weeks. RV advised there were some vacancies in the unit.</p>	
<p><b>18.</b></p>	<p><b>Update from Wales</b></p> <p><u>Activity based funding model</u>  AN advised the review of the activity based funding model is due to begin tomorrow.</p> <p><u>Personnel</u>  AN advised following secondment and resignation there were some vacancies in the team.</p>	
<p><b>19.</b></p>	<p><b>UKREDG update</b></p> <p>The group noted the action and information log would be circulated out of session.  <i>Action: ST to circulate UKREDG log out of session</i></p>	<p><b>ST</b></p>
<p><b>20.</b></p>	<p><b>Out of session items</b></p> <p><u>Applying a proportionate approach to the process of seeking consent</u>  The group noted the revised guidance had been circulated out of session. The group agreed to send any further comments to AH.  <i>Action: All to send comments to AH</i></p>	<p><b>ALL</b></p>
<p><b>21.</b></p>	<p><b>Any other business</b></p> <p><u>Digital Economy Bill</u>  The group noted, as the Bill stands at present, it may be interpreted that health related data is excluded from the Bill however the group noted its inclusion is currently being considered.</p>	
<p><b>22.</b></p>	<p><b>Date of next meeting</b></p> <p>Tuesday 22<sup>nd</sup> November 2016, 1pm – 4pm</p>	