

Ethics and Confidentiality Committee (ECC) Meeting – Thursday 20 September 2012

Members:

Dr Andrew Harris (Chair), Dr Mark Taylor, Dr Tricia Cresswell, Ms Alison Emslie, Mr Colin Harper, Mr Stephen Hinde, Professor Julia Hippisley-Cox, Ms Gillian Wells, Dr Chris Wiltsher and Mr Terence Wiseman.

In attendance:

Dr Alan Doyle (*NIGB Director*), Ms Natasha Dunkley (*Approvals Manager*), Ms Claire Edgeworth (*Deputy Approvals Manager*), Mr Martin Frowd (*Senior Business Support Officer*), Mr Mathew Fry (*NIGB Operations Manager*), Mr David Knight (*Department of Health*) and Ms Janet Wisely (*Chief Executive, Health Research Authority*) (item 3).

1. Welcome and apologies

Apologies were received from Mrs Pauline Brown, Dr Tony Calland, Dr Robert Carr, Dr Patrick Coyle, Dr Fiona Douglas and Dr Jane Kaye.

2. Health Research Authority (HRA) Transition discussion

In order to support the establishment of the new advisory function, Members agreed to review the current person specification for NIGB ECC members. It was agreed the skill mix was very important as no one Member was likely to have the full skill set desired. The option of targeted recruitment of Members with particular interests, where justifiable, was suggested. Generic skills (to be held by all Members) and specific skills (to be held by at least one Member) were discussed. The outputs from this exercise would be taken forward by the project team, including Mr Mathew Fry and Ms Natasha Dunkley, supporting the transition in order to develop a draft person specification.

The Committee noted that the Establishing Chair would serve in that capacity until 31 March 2014 whereupon a new Chair would be appointed. It was suggested that all Members in post as at that time would be eligible to become the new Chair and to provide input into the process of appointing the new Chair. It was also suggested that the six Members appointed through direct transfer would serve until 31 March 2014; other existing Members who were appointed through open competition would serve for three years; and new Members from outside the current Committee would serve for five years. The HRA had guaranteed that the appointments process would be credible and transparent. The makeup of the appointments panel had yet to be confirmed but might include an HRA non-executive director; it was agreed that it would be inappropriate to include the HRA Chief Executive as this would weaken the element of independence in appointments.

Dr Mark Taylor, as Establishing Chair of the new advisory function, provided an update that all Members of the NIGB ECC had been invited to apply to be Members of the new advisory group that would succeed the ECC. It had been identified that it would be prudent to ensure that a maximum number of six Members transferred for a shorter period of appointment to guarantee continuity into the new advice function and to support the effective induction and operations.

A suggestion had been made by an ECC Member, supported without dissent, that the Committee collaborate to identify the initial six Members that would be nominated for direct transfer. Following that suggestion, Dr Taylor had invited individuals to indicate directly their suggested six Members so that consensus could be discussed at the meeting on the 20 September. Those that expressed an intention not to be considered were excluded.

Following review at the meeting, (and comment from those unable to attend the meeting), it was identified that three names had the consistent majority of nominations. These were Dr Tricia Cresswell, Dr Tony Calland and Professor Julia Hippisley-Cox. There was less consistency between the other suggested names and it was agreed that the Committee adopt a two-stage process to the nominations.

It was agreed that the three named individuals would be recommended as transferring into the new advisory function. It was also agreed that the Committee would identify three further Members who could effectively complement the strengths of these three. Following review of the person specification, the view was confirmed that significant lay representation was essential in providing a balance to the considerations of the advice function. A list was drawn up of lay Members of ECC who had not previously indicated that they did not wish to be considered for direct transfer. At this point, a number of Members removed themselves from the list, because they did not consider themselves to be lay, to be sufficiently lay, or for other reasons. A suggestion was accepted that the final three Members should be selected by vote. Members present were invited to select, by private ballot, three further Members, selecting at least two of their preferred three from the list of lay Members now displayed. The third preference could be anybody currently serving on the Committee, whether previously identified in any list or not. Dr Chris Wiltsher, Mr Terence Wiseman and Ms Gillian Wells received the most votes. In order to receive views from those not present at the meeting, it was agreed that Dr Mark Taylor would correspond with all members, informing all those present and not present of the process, and inviting further comments or any dissatisfaction with the process, within a specified timescale.

The Committee noted that the HRA would ultimately own the process of making appointments to the new body, but would seek input from multiple parties. The final size of the new Committee had still to be confirmed but was currently likely to be seventeen in total including the Establishing Chair. Of these, six would be directly transferred from the existing Committee (seven including the Establishing Chair, Dr Mark Taylor) and a further ten would be via open competition. Existing Members who were not transferred directly to the new Committee would be able to apply, but if successful would be appointed for a shorter term of office than new applicants unconnected with the current Committee. The aim was for a mixture of existing and new Members to improve the independence of the new Committee while enshrining organisational memory and continuity within it. The Chair advised Members that new Members would operate on the terms and conditions in place for Research Ethics Committee Members and thus would receive no honorarium for attendance at meetings from 1 April 2013 onward, although expenses would be claimable. Existing Members who transferred to the new Committee would have the option of remaining on their existing terms and conditions.

Mr Mat Fry, NIGB Operations Manager, advised the Committee that he sits on the transition project group handling the transfer of the Secretariat to HRA employment, which in turn reports into the Transition Board. Dr Alan Doyle, NIGB Director, added that the Department of Health were supportive of the staff transfer. The Chair raised concerns relating to staff capacity after the transfer, including the training of new Members and a slightly increased emphasis on advice by staff rather than Members, and to the accountability of staff. Members praised the enormous amount of background work done by staff under the current system. It was felt that some teething problems would be inevitable after the transfer, and it was noted that between January-April 2013 the Secretariat would have to support both the existing Committee and the new CAG in shadow form.

3. Discussion with the Health Research Authority Chief Executive

The Committee welcomed the attendance of Ms Janet Wisely. A helpful conversation took place where members updated Ms Wisely on the activities that had earlier taken place. Ms Wisely provided further details on proposals for the advisory function and terms and conditions of HRA appointments. Ms Wisely reiterated that existing Members could apply through open competition and would be appointed to a three year term if successful; new Members recruited from outside would be appointed to a five year term in line with existing Research Ethics Committee appointments.

The Chair raised concerns on behalf of the Committee relating to the balance of existing versus new Members on the new body, citing the need to preserve business continuity and existing expertise while emphasising independence. It was felt that the new body would need to manage conflicts of interest

very effectively where stakeholders might have conflicting agendas, in order to continue to properly balance individual confidentiality against public interest considerations. The Chair also noted that the Committee had raised concerns around the capacity of staff during and after the transition period, and clarifying issues of accountability. Members suggested that improvements would continue over time and that therefore ways of working in the new function would initially seem very similar to those of the current Committee but might later diverge. The importance of maintaining a good skill mix within the function was agreed.

The importance of lay membership and input was agreed by all present. Ms Wisely noted that Research Ethics Committees have a minimum threshold of one third lay membership. The Chair advised that three of the six Members who had been chosen for direct transfer to CAG were identified as lay.

Ms Wisely advised the Committee that listening events had been proposed to take place during the transition period and confirmed that integration of the Secretariat staff into HRA was an area under discussion. HRA currently comprised three divisions – Operations, Finance and Corporate, and Improvement. Research Ethics Committees were part of the Operations division. The intention was for the CAG and its Secretariat to be hosted within Improvement in the first instance, possibly transferring to Operations subsequently but retaining clear separation from the REC role. Members praised the importance of the work of the Secretariat outside of meetings, and noted that the shortfall in staffing at NIGB had impacted on this work. Ms Wisely confirmed that the HRA intention was to ensure sufficient staff support and that this aligned with the need to properly resource support for the RECs.

Ms Wisely noted that the Committee currently advises the Secretary of State for Health who makes the final decision on applications for access to patient identifiable data. Under the new system, the HRA would be the approving body for research applications. Non-research applications were likely to remain with the Secretary of State, although this might change in future. The Committee were asked for their opinion on whether the final authority to approve research applications should be placed within the advisory function or rest elsewhere in the HRA. The majority of Members strongly agreed that the strength of the current committee was the ability to provide independent and transparent advice. Members emphasised the continued importance of transparency, and noted an appeals policy already exists where applicants are unhappy with decisions, albeit currently via NIGB. The Chair reminded Members that the legal liability rests with the actual data controller, or discloser, and that approval under the Regulations only provides a legal relief from a breach of confidentiality, and that data controllers operate within a number of local frameworks.

Members highlighted a lack of education in the medical research community with respect to the application process, and suggested HRA could have a role in improving education and raising awareness. Ms Wisely confirmed that a project was in development, supported by staff seconded from the Medical Research Council who would work with funders as well as researchers. Members particularly emphasised the need to encourage patient engagement and involvement through better researcher education, as many applicants currently fail to budget for patient engagement.

4. Next Steps in Transition

The Chair praised the Secretariat and in particular Mr Mathew Fry, NIGB Operations Manager, for the excellent work of the Business Improvement Programme.

Members asked Dr Mark Taylor, as Establishing Chair of CAG, to set out his expectations during and beyond the transition period to full establishment of CAG in April 2013. These included further meetings between Ms Janet Wisely and the Committee (either as a group or separate one-to-one sessions); continued development of the Business Improvement Programme; a review of existing themes; and an assessment of priorities before the influx of new Members. The process of appointing Members and the future Chair in an independent manner had still to be determined. The intention was for new Members to be appointed by February 2013 and invited to the February meeting of the Committee as observers, potentially paired up with existing Members, as part of the induction process. It would be useful to run the first day of the February meeting as a “mock” day providing training for

new Members, and the second day as the “real” meeting with recommendations, but this was subject to the constraints of staff capacity to support and the volume of applications received, which would not be possible to predict until closer to the date of the meeting. If this proved to be impracticable, a separate training session for new Members could be scheduled instead. It was noted that as the February 2013 meeting would be the last one under the auspices of NIGB and the existing system, the volume of applications could be unusually high. Members suggested that existing and new Members, paired together, could review applications jointly in advance of the February meeting. The Chair suggested that a framework for decision making, based on the outputs of the Business Improvement Programme, should be developed before new Members received any applications, and that the Establishing Chair should have regular one-to-one discussions with all Members.

The Chair expressed his satisfaction with the outcome of discussions with HRA to date, and praised the Committee and Secretariat for all their hard work, which had helped to ensure that a unified advice function would be transferred to the HRA and final decision functions would go to the HRA or remain with the Secretary of State, rather than both advice and decision functions being split between the HRA, NHS Commissioning Board and Public Health England as had been proposed earlier in the year. The Chair welcomed the continued advisory role of the new function on the basis that this would be seen as an aid rather than a barrier by the wider research community.

4. Upcoming meeting dates

5 and 6 December 2012

7 February 2013