Ethics and Confidentiality Committee (ECC) Meeting – Friday 20 July 2012

Members:

Dr Mark Taylor (Chairing), Mrs Pauline Brown, Dr Tony Calland, Dr Robert Carr, Dr Patrick Coyle, Professor Julia Hippisley-Cox, Dr Tricia Cresswell, Dr Fiona Douglas, Ms Alison Emslie, Mr Stephen Hinde, Ms Gillian Wells (*departed at 12pm*) and Mr Chris Wiltsher.

In attendance:

Dr Alan Doyle (*NIGB Director*), Ms Natasha Dunkley *(Approvals Manager),* Ms Nicola Gould (*NIGB NHS Information Governance Lead)*, Mr David Knight (*DH External Relations*)

1. Welcome and apologies

Apologies were received from: Dr Colin Harper, Dr Andrew Harris, Mr Stephen Hinde, Professor Jane Kaye and Mr Terence Wiseman.

2. Update on 's251' arrangements.

Mr David Knight, the Department of Health Senior Civil Servant and NIGB sponsor, provided an update on progress against transitional arrangements of the advice function to the Health Research Authority. He updated the Committee that a ministerial briefing had recently been submitted setting out the proposed approach, confirmed that an advice function would continue to advise the relevant bodies, and that the approval function would not change as that would require a change in the Regulations to be considered again at a later date. The approvals function for research applications would transfer to the Health Research Authority, with other types of approvals remaining with the Secretary of State for Health. The secretariat would also be likely to transfer to the Health Research Authority and plans were being developed to manage this.

Members thanked Mr Knight for attending and raised a number of points, one of which emphasised the importance of ensuring that appointments were made in an open and transparent manner so as to maintain public and professional confidence in the advice function. Members also indicated the importance of having adequate lay membership on the function. Members queried the process by which advice would be provided, and expressed the hope that this would continue to be transparent, which was confirmed.

Members thanked Mr Knight for the informative discussion, found many aspects to be reassuring and welcomed the opportunity to discuss further points raised within the discussion outside of the formal meetings.

3. Clinical Practice Research Datalink Service presentation

Members welcomed the opportunity to discuss the application, and found it to be helpful in gaining an initial understanding of how the fully operational service was to be developed. The primary purpose of this item was to seek advice and comment from the Committee, prior to a formal submission being made in September 2012.

Dr John Parkinson attended to present to the Committee an overview of the Clinical Practice Research Datalink (CPRD) Service, as a precursor to a formal application covering linkage to additional datasets. Comments were focused around the presentation (see Appendix 1) that provided information on the end to end approach to data stewardship. The Medicines and Healthcare products Regulatory Agency (MHRA) would be the data controller, and the Health and Social Care Information Centre (HSCIC) would

be the data processors acting on behalf of the MHRA. The MHRA would not be processing confidential patient information for this purpose. It was understood that a memorandum of understanding would be developed to manage the relationship between the MHRA and HSCIC.

It was noted that in incorporating the GPRD and RCP pilots, the remit of CPRD would move from general practice to clinical practice. Definitions of anonymisation were queried and explored, and the potential identifiability involved in disclosures was highlighted.

Appreciating that this was an initial discussion, members indicated that they would expect to see clarity over the aspects that the service were intending to seek approval for, and this should be clarified through clear headings and the individual datasets covered under each section.

The importance of adequate patient and public involvement was highlighted, and noting the response that patient involvement was inherent within GPRD, members commented that this appeared to fulfil an excellent information provision role, rather than active patient involvement with the activity.

Queries were raised over how dissent would be managed, and it was confirmed that when notified, the Health and Social Care Information Centre would be notified of the request in order to process it. It was also confirmed that the MHRA would have the right of audit. It was confirmed that the CPRD would also be carrying out processing when consent in place, and this aspect would fall outside the remit of the Committee.

Members discussed the potential identifiability within disclosures, and queried how this would be managed. Dr Parkinson confirmed that an Independent Scientific Advisory Committee (ISAC) would be reviewing this aspect, and the suggestion was raised for the Ethics and Confidentiality Committee to work alongside the ISAC in the initial establishing phases of CPRD. This option was discussed and an advantage raised that it would provide an independent source of expertise for difficult applications. Suggestions also focused on developing a set of principles that would identify when a detailed review or application would be advised to be submitted to the Ethics and Confidentiality Committee. This could also establish a process on how to proceed when an application was submitted to CPRD where the consent was not deemed valid to enable the processing. Analogies were drawn between this aspect and previous work with the DMsG and current liaison with the HSCIC's DAAG group. This suggestion was welcomed by Dr Parkinson, and it was agreed that this arrangement would be investigated and developed further.

The Ethics and Confidentiality Committee meeting to consider applications was concluded at this point.

4. Evidence gathering session – Information Governance Review panel

The remainder of the meeting covered the Information Governance Review and the evidence presented by the NIGB Ethics and Confidentiality Committee in terms of key principles it had developed throughout its assessment of applications to lift the common law duty of confidentiality. This part of the meeting was chaired by Professor Martin Severs.

Discussions ranged from the rationale for the establishment of the Patient Information Advisory Group and subsequently the Ethics and Confidentiality Committee, the importance of balancing two public goods; confidentiality and research, considerations around consent, the increasing use of de-identification techniques and technological developments within this area. Comments were also made around the importance of public perceptions of the system, the importance of appropriate lay representation, continued development of principles and improved decision-making, and perceived and actual independence of the body in the future as often data controllers will rely upon the advice and subsequent approval in their own decision-making, and the need for it to continue to provide robust advice.

Members also discussed the importance of education as often poor applications arose from a lack of understanding of the issues around confidentiality. The importance of retaining the learning from previous assessments should be retained and built upon in the future. The ECC concluded by reiterating that the Committee itself was a facilitative one, in that it advises where a legal gateway should be put in place to legitimise essential secondary use activities, with due regard to other governance requirements. It also provided a clear check and balance to the system, and the Committee expressed the hope that suitable checks and balances would continue to remain in the system in the new arrangements.

A summary of the ECC points will be incorporated into the final report.

Meeting ended.