Ethics and Confidentiality Committee (ECC) Meeting – Thursday 7 February 2013

ECC Members:

Dr Mark Taylor (*Chair*), Mrs Pauline Brown, Dr Tony Calland, Dr Robert Carr, Dr Patrick Coyle, Dr Tricia Cresswell, Dr Fiona Douglas, Ms Alison Emslie, Mr Stephen Hinde, Professor Julia Hippisley-Cox (*items 1-3a*), Ms Gillian Wells, Mr Terence Wiseman and Mr Chris Wiltsher.

In attendance:

Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(Deputy Approvals Manager) (items 1-2),* Mr David Evans *(Information Commissioner's Office),* Mr Martin Frowd *(Senior Business Support Officer)*

For specific items:

Mr Alan Barcroft (*Medicines and Healthcare products Regulatory Authority*) (*items 3-4*), Mr Andy Boyd (*University of Bristol), (item 2*), Ms Emma Gordon (*Office for National Statistics) (item 3),* Professor John Macleod (*University of Bristol*) *(item 2),* Dr John Parkinson *(items 3-4*), Ms Clare Sanderson *(Health and Social Care Information Centre) (item 3),* and Ms Lucy Vickers (*Office for National Statistics) (item 3).*

1. Welcome and apologies

Apologies were received from Mr Colin Harper and Professor Jane Kaye.

2. Project to Enhance ALSPAC through Record Linkage (PEARL): The enrolment of the remaining eligible cohort to ALSPAC (ECC 9-02/2013)

This research application from the University of Bristol detailed contacting 4825 eligible individuals to invite them to enrol in the ALSPAC study. The application detailed that these individuals had not been enrolled by their families previously and may not have been contacted by the ALSPAC team in the past. The individuals would be identified as being born in the Bristol area between April 1991 and December 1992. Support was requested to allow ALSPAC to access address details from the Health and Social Care Information Centre (HSCIC) for the remaining eligible cohort who were not enrolled in the original study in order to write to them to seek consent to the PEARL linkage project. Professor John Macleod and Mr Andy Boyd had been invited to attend the meeting. Members welcomed the opportunity to discuss the application directly with the applicant.

Members requested further details in relation to the added benefits of moving to a complete geographical birth cohort over the current enrolled birth cohort. Professor Macleod explained that as well as providing greater statistical power, those who had enrolled in the ALSPAC cohort from birth were likely to be from a socially advantaged background and asserted that there was evidence that this was the case. It was explained that this would create bias that for some research questions would affect results significantly. Members suggested that it would be likely that the cohort would not represent the whole of the UK in any case as those born in any particular area were not likely to be a representative sample. Members queried how the applicant would overcome this issue and whether similar measures could be put in place to address the bias described. Professor Macleod explained that comparisons were made with data for the rest of the UK to identify bias in the ALSPAC cohort and make allowances; however including the eligible cohort provided a method to directly address the bias within the ALSPAC cohort.

Members queried what efforts had been made to make people aware that they might be eligible for inclusion into the ALSPAC cohort and therefore might receive an invitation letter and be included in the study. In addition, Members asked whether the applicant had considered approaching patients via GPs,

bearing in mind the size of the grant provided to ALSPAC, and raised concerns that the application stated that GPs would not be aware if a patient was enrolled in ALSPAC. It was reiterated that the application was requesting contact details only at this point in order to write to patients and that the method of approaching patients would be approved by a Research Ethics Committee. In relation to making the cohort aware of ALSPAC, Mr Boyd explained that ALSPAC had undertaken media campaigns, local events and outreach clinics to make people aware and opting in to ALSPAC straightforward. In relation to GPs making an approach, it was explained that this was considered to be an additional burden on GPs and that if this methodology was followed; response rates were likely to be low as GPs might be too busy to pass on requests. Professor Macleod explained that this had been reflected in previous studies. Additional funds would also need to be obtained in order to allow this approach to be supported and there would be a large number of GP practices to engage with. In addition, Professor Macleod explained that previous experience of sending out letters directly from researchers had resulted in very few complaints and where queries had been raised a full explanation had been provided which most were satisfied with.

Members noted that there might be other datasets which the applicant could use to obtain contact details for the eligible cohort, for example the electoral roll, in order to identify and write to participants, and queried whether the applicant had considered carrying out publicity campaigns to recruit to ALSPAC. Members explained that they were considering these alternatives as they would mean that a breach of patient confidentiality would not be required. Professor Macleod explained that publicity campaigns were already undertaken. Using NHS number to locate individuals was considered to be the best option as this would allow ALSPAC to target specific individuals that were definitely eligible, rather than writing to a larger cohort where some individuals may not be eligible. In particular, it was highlighted that there might be a greater risk in this approach as more people would be contacted and the approach would be less cost-effective as it would be in essence sourced from public funds. Additional concerns around using the electoral roll were highlighted: it was asserted that the enrolled ALSPAC cohort were particularly mobile and around half now lived outside the Bristol area and those who were less socially advantaged may be less likely to be registered on the electoral roll. Members commented that those who were less socially advantaged, whom the applicant was particularly interested in recruiting, might not be as mobile. In addition, Members queried whether the NHS data accessed would be accurate as often young people did not keep GPs up to date with address changes. It was recognised that this could potentially be an issue and noted that 20% of addresses had been determined as invalid in previous studies.

Members explored further the benefits that might be achieved by inviting the geographical eligible cohort to consent. Members queried whether, if response rates were similar to the current enrolled cohort at 27% or lower, how significant the inclusion of these very low numbers would be. In particular Members asked whether there were examples of research questions that would benefit from the additional power. Professor Macleod explained that this was hard to predict and the value would be dependent on the type of research questions that were being asked but that if a response rate of 27% occurred then this would equate to 1000 additional participants which would certainly not be insignificant and provide additional power to the study. Mr Boyd explained that ALSPAC data could be used with other cohort studies data and in these instances a few additional cases of rare conditions could be important. It was suggested that studies looking at the outcomes of drug use would benefit in particular by the inclusion of a broader, less socially advantaged cohort. The Committee queried what information would be included in patient letters and consent forms about the potential future application for support to link data under the Regulations, the result of non-response and how the applicant would ensure that response rates were as high as possible. It was explained that it was intended that there would be some reference to potentially applying to the Committee for support to access data on non-responders. Publicity campaigns would be run to alert people to the ALSPAC study and it was planned that responding would be made as convenient as possible. Members thanked the applicant for attending and agreed that the discussion had been useful.

Following the applicant's departure, Members discussed the application further. The Committee noted that the ALSPAC study was particularly important and agreed that they were supportive of the cohort study in principle. Members noted that although support was requested to allow contact details to be used to write to patients to request their consent, it is a requirement of the Regulations to ensure that there is a clear public interest in the disclosure taking place. With this in mind Members discussed the

justification for including a complete geographical birth cohort, and commented that in order to determine the benefit of writing to patients to gain consent to take part in the study, further information about the specific benefits and examples of research questions should be provided. It was agreed that the added value would need to be demonstrated prior to a recommendation of support being made. Members considered whether all alternatives to the use of NHS data had been explored and noted the discussion with the applicant in relation to the use of alternative data sources, such as electoral role or education data. It was agreed that further exploration of these alternatives should be undertaken as the Committee were unable to recommend support where potential alternatives which did not require the disclosure of confidential patient information without consent existed. Members recommended that if a further application was made, the applicant should include a full explanation as to why these alternatives would not be practicable. The Committee noted that the application form included some details of the PEARL linkage project and agreed that it should be ensured that if a future application was made this should be reduced to include only the details of the consent for consent aspect. This would ensure that an accurate record of any approval could be maintained. Members agreed that it would be important for the applicant to make significant efforts to ensure that those members of the cohort who were hard to reach were engaged with and requested further details regarding the additional publicity campaigns that were undertaken as part of this. In addition, Members suggested that the initial approach to the cohort should be straightforward, brief and allow the recipient to choose different levels of participation. Members agreed that they would need to see a copy of any patient information material as part of an application. The Committee noted that there was some uncertainty as to whether to include references to the applicant's intention to seek support to access data for those that did not respond and reiterated that this particular aspect was not currently being considered. In relation to this, Members queried whether the applicant had noted any change in response rates from the previously enrolled cohort when references to applying for support under the Regulations had been explicitly mentioned.

The Information Commissioner's Office (ICO) observer recommended that the applicant contact the ICO to ensure that the proposed processing, and in particular the fair processing information, was compliant with the requirements of the Data Protection Act 1998.

Members agreed that the application did not currently demonstrate that the minimum requirements of the Regulations had been met and therefore could not provide a recommendation of support at this time. Members advised that the applicant explore the alternatives discussed: if these proved not to be feasible, the applicant was invited to resubmit the application, addressing the following points: a clear and demonstrable public interest in the inclusion of the geographical birth cohort, with examples, even if response rates only allow a small amount of additional data to be included; evidence that alternatives to the use of patient information, including electoral roll and education data, had been explored and why these approaches would not be feasible; refinement of the application form to include only the request to access address details for the purposes of writing to the cohort to gain consent; clarification on how the applicant would attempt to engage with hard to reach members of the entire geographical birth cohort. Any resubmission should also include all patient information material, with confirmation of liaison with the ICO to ensure that all patient information materials were compliant with the requirements of the Data Protection Act 1998.

3. 11.30am - ECC principle development: status of date of death within context of the Regulations [ECC 9-03/2013]

The Chair introduced this item by noting that the ECC provide advice on the application of the Health Service (Control of Patient Information) Regulations 2002. The parent Act, the National Health Service Act 2006, defines confidential patient information (s251(11)). Date of death can only be confidential patient information if it satisfies the definition of patient information contained in section 251(10), and if the identity of the patient is considered to be ascertainable, it would subsequently fall within the definition of confidential patient information. Ultimately, if considered to fall outside the scope of the Regulations then access and onward disclosure of date of death would not be an issue, however, the Chair indicated that applicants would need to know if it is confidential information in common law. The Committee had invited representatives from CPRD, Q-research, the HSCIC and ONS to discuss their views on whether in a specific context, date of death is or is not an identifier. Legal advice had been sought prior to the meeting but it had proved inconclusive, therefore views were sought from attendees to identify and

explore applicable characteristics that could help to inform the judgement, with a view to a position paper being developed by the Committee. It was the shared understanding of all attendees that date of death is an essential item for many secondary use activities such as investigating new medicine safety, and the specific issue for consideration was the position as to date of death within the remit of the Regulations.

Each of the invited representatives provided a summary of their current approaches to disclosure where date of death was included, and an overview of the governance checks in place.

ONS hold and supply death data under the stringent requirements of the Statistics and Registration Services Act 2007. They indicated their position that fact or dates of death were not considered identifiable or disclosive in their own right. However, the addition of sex, age at death, specific cause of death, place of residence, LSOA, marital status and occupation would render the dataset to be identifiable and they would not publish a dataset including these items. Where underlying cause of death is required they classify into 5-year age bandings. A brief discussion took place over three types of data disclosure. The first is identifiable where the dataset clearly contains identifiers such as NHS Number, date of birth, postcode. The second type is considered to be disclosive, where using the dataset as a basis it would be theoretically possible to gain more information about a person, but the dataset itself does not contain strong identifiers. The third category is clearly non-disclosive where there is no reasonable possibility for patient identity to be ascertainable. However, ONS confirmed that they do not make a distinction between disclosive and identifiable and noted that it is easy for a dataset to become identifiable. Q-research indicated that they do not provide any free text and following a risk assessment, typically disclose a sub-set or sample of the overall dataset as a measure to ensure non-identification. CPRD highlighted that a legally binding contract is put into place and other risk mitigation measures to help ensure that the disclosure of identifiable data is unlikely.

Extracting key points from all discussions, it was summarised that in considering whether a dataset including date of death is identifiable, then four aspects should be taken into account:

1. The totality of data items contained within the dataset
2. Access / governance controls in place and restrictions placed on recipients
3. Number of patients potentially covered within that specific grouping
4. Whether the recipient will receive the full dataset, as if receiving a sub-set of the overall dataset this would significantly reduce any possibility of re-identification.

The proposition was tested that if date of death is included within the dataset, and if the dataset itself does not include any other strong identifiers, then the risk of re-identification is such that it is not rendered identifiable. However, it was noted that an accretion of ‘weak’ identifiers could render the dataset identifiable, therefore the importance of having controls in place to ensure the dataset remains de-identified would be crucial. The issue of a unique attribute was also highlighted as regardless of whether it is a small or large dataset, a unique attribute will remain unique and therefore potentially identifiable. Members noted the helpful categorisation of datasets into identifiable, disclosive (where the controls in place render the dataset as not identifiable and therefore not requiring section 251 support for onward disclosure) and non-identifiable was a helpful distinction, although it would need to ensure there is sufficient alignment with forthcoming guidance being issued via the HSCIC.

Members thanked attendees for their time and noted that further work was needed to follow-up on the discussion, and that future input would be strongly welcomed.

4. Consideration of CPRD narrative update on application [ECC 5-05 (a)/2012]

CPRD is the output of a government commitment for a managed health research data service where anonymised linked NHS data is utilised within research activities. The processing and linkage of confidential patient information will be carried out by the Health and Social Care Information Centre (HSCIC), on behalf of and under governance arrangements agreed by the MHRA (CPRD). Patient identifiers will be separated from clinical research data at data source origin, and the HSCIC will receive the patient identifiers and carry out linkages on behalf of CPRD through their Trusted Data Linkage Service. This application included details of the main application, the memorandum of understanding

with the HSCIC, proposal for a system of approval for dataset linkage within CPRD by ISAC, REC favourable opinion letter, data stewardship diagrams and practice information leaflets. Members reviewed the original application discussed at the September 2012 meeting, supplementary responses provided in response to queries, and the narrative report provided for the February 2013 meeting. The Committee welcomed the attendance of Dr Parkinson and Mr Barcroft. Members were broadly satisfied with the details of the documentation, and while some aspects were found to be slightly unclear, agreed that reasonable steps had been taken to seek to address previous issues. It was clarified that the MHRA was the data controller and the Health & Social Care Information Centre (HSCIC) would be the data processor.

In particular, the revised position of ISAC and proposal to manage disclosures of potentially identifiable information were welcomed. It was noted that there was a risk that onward disclosure could be potentially identifiable, and while the measures in place appeared to be strong so as to mitigate against this risk, Members indicated that agreeing disclosures and reporting retrospectively could mean that a disclosure would have taken place where it was subsequently indicated to be disclosive of an individual. It was felt that a more cautious approach should be taken to support this issue in the forthcoming months, therefore Members suggested that the most appropriate way to manage this risk would be for a regular reporting schedule of disclosures, timed to coincide with each formal meeting schedule of the Confidentiality Advisory Group. This would also help develop criteria, thereby improving clarity for all parties as to where referral to the Group would and would not be required. It was also noted that there would be a requirement to add additional data sources. The Committee was clear that approval could only be applied to those data sources that clearly fell within the scope of the Regulations and CPRD should ensure they were clear where the data was derived from. Members were open to a proportionate review consideration of additions to the list of data sources, and advised that this be formalised at the first Confidentiality Advisory Group meeting.

Members noted the comment around access to sexual health information and were clear that the approval could only provide relief from the common law duty of confidence as the onus remained on the applicant to ensure compliance with all other relevant legislative provisions. It was noted that the approval covered information generated in England and Wales, and currently the scope of the Regulations applied to NHS generated or NHS-commissioned patient information. Information falling outside the scope of this approval must be processed under another clear legal basis. Members queried the inclusion of methodological research in the general purposes for which data would be accessed, and felt this to be extremely broad. Members advised that this aspect would currently be excluded from the approval, but could be revisited if the applicant wished to refine the extent of this aspect. It was noted that CPRD was intended to incorporate the approvals already provided to GPRD. The intention was for the GPRD applications to expire by 31 March 2013 and be incorporated into this application. As the narrative report and query responses had changed, the applicant was advised to seek clarity from the Research Ethics Committee who had previously provided a favourable opinion to identify whether any further amendment was required.

Members concluded there was sufficient evidence that the threshold within the Health Service (Control of Patient Information) Regulations 2002 had been met, and therefore agreed to provide a recommendation of support to the Secretary of State for Health, subject to organisational compliance with all other applicable statutory provisions and best practice guidance including specific legislation governing access to sensitive data such as identifiable sexual health information; review of disclosures at each Confidentiality Advisory Group meeting for an initial 12 month period, with review of the process at 6 months; confirmation of compliance with the Data Protection Act 1998; and exclusion of methodological research as a purpose for which information could be disclosed.

5. Any other business

The Chair thanked all Members, those transferring to the new Confidentiality Advisory Group and those standing down at the end of March 2013, for their contribution to the work of the Committee.