Data Access Advisory Group

Minutes of Meeting held 20th September 2011

Members: Clare Sanderson, Sean Kirwin, Patrick Coyle, Dr Mark Davies

In attendance: Susan Milner, Tom Latham, Dawn Foster, Diane Pryce, Vanessa Kaliapermall, Olivia Podesta-Atkin (Secretariat)

Apologies: Kuldeep Sohal

200911-a	**Welcome** Dr Mark Davies welcomed everyone to the meeting.
200911-b	**Minutes of the Previous Meeting** The minutes of the previous meeting were ratified. A summary of actions from the August meeting are as follows: <u>Application security assessments and IG Toolkit</u> CS had meeting with Phil Walker (DH) to discuss the implications of incorporating the proposed IG Toolkit assessment into the evidence to be used in the approval process. Whilst there is no objection to the concept, there will be an impact on the NHS IC as an organisation related to resource and monitoring of Toolkit assessments. PW is preparing a document for consideration. This will be passed to the Group for further discussion. It was also agreed that input from ECC would be required as they will also be using this method of assessment in Section 251 approvals. **Update: There is a workshop planned for 11th October to take this forward.** <u>190411-c - University Hospital Birmingham</u> As reported at the last meeting, the Protocol for access to Consultant Code had been received but was not considered adequate. The customer was asked to provide details of the access controls which would be in place for access to the national consultant data. Further details have been received and the customer was advised that this is nearly there, however there were a couple of issues which needed further clarification. This has not yet been received. <u>190711-a - Dr Foster Intelligence</u> Request from Dr Foster Intelligence to allow them to receive clear sensitive data and diagnoses provided to Dr Foster Unit at Imperial College under the current Section 251 support granted to Imperial College. This application was not approved and the applicant advised of the Group's decision and requirements. No further contact has been received by DAIS team from the applicant. <u>Requests for access to restricted data fields through HES Business Objects</u> At a previous meeting, the Group requested that a robust process be put in place for requests for HES sensitive and identifiable fields through the on-line business objects function. A draft application form was circulated for consideration by the Group. The application form was approved by the Group.

	230811-a – University of Cambridge Request for MHMDS including sensitive data. This application was approved at the meeting subject to approval of the SLSP. We have now received confirmation that the SLSP has been approved. The applicant has been offered pre-release access to the data by the MHMDS team and this is awaiting approval by Head of Profession. PCMD – Proposed linkage of MHMDS with Primary Care Mortality Database Following the discussion at the last meeting regarding linkage of MHMDS to PCMD, it has been confirmed that the NHS IC are not the data controller. The IC maintains the database on behalf of DH. Access to the database requires ONS approval, as with any access to death data. A process is in place for access and a piece of work is currently being carried out by the NHS IC to ensure this is well documented. East Midlands Health Observatory – request for SUS/HES data Request to receive Consultant Code not approved. Customer is being provided with non-sensitive data.
200911-c	**Matters Arising** **a) Overview of outstanding applications** MR1251 - UCL Institute of Child Health - Safety and appropriateness of growth hormone treatments in Europe (SAGHE) At the 23/08/2011 meeting the Group requested clarification about whether the person contacting the patient was appropriate. If this would be a member of the care team then this would be acceptable, however, if contact was to be made by the researcher, then Section 251 support would be required. The Group advised that this application could be approved out of committee, subject to clarification regarding consent. **Action: DP to provide clarification regarding consent.** **DP confirmed that the researcher has clarified that the initial contact would be made by the patient's current endocrinologist.** MR1252 – ICNARC, Tavistock Square, London DP had submitted this application for Chair's action to the 23/08/2011 meeting; however this was brought to the Group for consideration in his absence. The Group agreed that the consent was acceptable and mentioned that this was a good application. The application was not clear however regarding who would make contact with patients without capacity. The Group requested clarification on whether the person providing advice was appropriate. There was also no mention of power of attorney in place. The Group gave conditional approval subject to appropriate representation for patients without capacity. **Action: DP to provide clarification regarding consent for patients without capacity.** DP contacted the customer for clarification, customer response; Consultees give agreement in line with the Mental Capacity Act, - patient consent would be sought from patients when they regain capacity. There may be a low number of patients who are not consented following agreement from a Consultee this would likely be because they do not regain mental capacity when they leave the hospital. The group were content with this and gave approval. **(b) Decisions Out of Committee**

OC/HES/014 – Centre for Suicide Prevention

This application is an update to enable the Centre for Suicide Prevention to receive data for the time period 01/04/2009 – 31/03/2011 inclusive.

The applicant has ECC approval (PIAG 4-08(d)/2003) to receive the identifiable data items Date of Birth and NHS Number. The sensitive items, Consultant Code Local Patient Identifier and Code of patient's registered or referring general medical practitioner are also required.

The group approved the extension of the data years.

(c) Other

MRIS - ECC Statement re MRIS death data, including case study (MR1222)
The Group had previously requested that a letter be sent to ECC by DP. DP had confirmed that the letter had been sent and is awaiting ECC's response.

Update: The group has still not received a response to the letter sent to the ECC. Diane to contact them again.

Responsibility for Cancer data – requirements for the researcher

Background:

When ONS first started running the Medical Research service and providing death and or cancer data to research studies the policy was to refer all studies requesting cancer data to a committee who were from the BMA. This committee would consider if it was appropriate to release data to the researcher. In turn the researcher was required to have a nominated person registered with the GMC to take 'clinical' responsibility for the cancer data.

After the passage of time the BMA committee were disbanded and the responsibility was transferred within ONS. At that time ONS employed a number of medics and it became policy to refer requests for cancer data to a medic with 'expert/specialist' knowledge in the field. It was still a requirement for the researcher to nominate a responsible person.

This practice continued until we transferred from ONS to the NHS IC and at that time it was agreed that the responsibility to consider requests for cancer data would transfer to the new committee i.e. DMsG.

This subject was discussed at the meeting following a statement from ONS that they believed it is no longer necessary to ask researchers for this.

The Group are happy with the rules in place to protect sensitive data as it is and feel there is no need for extra restrictions for cancer data.

Consent Models:

CS raised some issues around whether the current consent model was "appropriate". There have been a number of queries regarding the decisions made by the Group relating to previous consent. Discussion followed on the appropriateness for the Group to request that applicants re-consent their cohort to the current consent wording where longstanding existing consent is in place.

The Group were of the opinion that each consent application needs to be considered on its own merits, taking into account when the consent was initially gained and whether the consent statement used was sufficient at that time. It was agreed that where existing consent is in place, but does not match the current agreed wording, the above should be taken into account by the Group. However, where the original cohort is contactable, every effort should be made to advise them of the new wording and asked to confirm their agreement. Whilst it is sometimes difficult to have regular contact with the cohort, it was mentioned that contact is sometimes made by newsletter and therefore this might be a way of informing them of any changes to the consent.

In the case of prospective studies (i.e. those where patients have not been recruited as yet) these must continue to use the DAAG approved wording.

	CTSU – University of Oxford Consent request was submitted to the NHS IC but did not meet the current model. In line with DAAG's guidance, the applicant was asked to re-consent his cohort. Subsequently a letter was received from the applicant to request guidance on obtaining access to HES data for patients in the MRC/BHF Heart Protection Study. CS had a phone call with the applicant to discuss the consent form on 12th September, and therefore raised the application for consideration by members. The Group felt that the information leaflet and consent form, in particular the reference to central registries, was not sufficient to cover centrally held electronic health records. 180111-d - Brighton and Sussex Medical School (BSMS) The applicant requested the sensitive field Local Patient ID, as well as the identifiable fields Date of Birth – Patient and NHS Number. Brighton and Sussex Medical School provided an update on the wording of their consent documentation back in March. The amended wording was discussed on the 7th April at the Brighton Research Ethics Committee. They received ethics approval to re-consent the patients in this study so that they now consent to give access to "any medical information held on them in National databases (the Hospital Episodes Statistics and NHS Information Centre databases)". The applicant therefore wrote to the patients involved in the study asking them to sign an amended consent form. Brighton and Sussex Medical School updated DAAG on the consent situation. The applicant has said that there have been a few forms coming through to them, but they now feel that they will not receive any more. About 75% of study participants have so far returned the amended consent forms. The applicant has asked what their next step would be. The group advised that whilst 75% of the cohort has given their consent, there remains 25% who have not responded. It will therefore be necessary to approach ECC for advice regarding whether it would be appropriate to obtain Section 251 support for the remaining 25% of the cohort.
200911-d	**HES Applications** No HES applications were submitted to the meeting.
200911-e	**NHS Central Register – MRIS Applications** Notification to committee: MR1246 – Salford Royal NHS Foundation Trust MR1248 – Leeds General Infirmary MR1256 – Stockport NHS Foundation Trust MR1260 – CJD Section, Health Protection Services, London
200911-f	**Any other business:** DAAG Website link A link to the website was circulated to the Group for feedback. Diane Pryce requested that the link to the medical research page start at the home page rather than further into the site. **Action: Susan Milner to amend the webpage link and Group to provide feedback on website.**
	Date of next meeting: 18th October 2011