Data Access Advisory Group

Minutes of Meeting held 8th November 2011

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

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

Apologies: Vanessa Kaliapermall

081111-a	**Welcome** Dr Mark Davies welcomed everyone to the meeting and apologised for cancelling the last meeting at short notice.
081111-b	**Minutes of the Previous Meeting** The minutes of the previous meeting were ratified. <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:** A workshop took place on 11th October to take this forward. The group has not received the document from Phil Walker yet. Concerns were raised that using just IGT scores rather than reviewing an SLSP may not be robust particularly where customers may be part of a commercial arm of an organisation that completes the IGT. The use of Honorary contracts in universities was also discussed and the fact that the NHS would be unable to take disciplinary action should a breach of confidentiality occur. **Action:** DF to contact Phil Walker regarding the document; MD to write to PW to outline the concerns of DAAG.
081111-c	**Matters Arising** **a) Overview of outstanding applications** MR1250 – this application is still being discussed with ECC. **(b) Decisions Out of Committee** None **(c) Other** None
081111-d	**HES Applications** <u>181011-a – University of Aberdeen</u>

The applicant is researching the outcomes of knee replacement operations. However, there are many different types of knee replacement available and it is not clear which are best, or whether some are more appropriate for some conditions than others.

The Knee Arthroplasty Trial (KAT) aims to answer some of these questions. The Trial involves 1500 people undergoing knee replacement surgery, and is made up of four main questions around different prostheses or procedures used in the surgery.

The first part of the study is designed to clarify whether a knee replacement involving a metal component or a metal and plastic component is most suitable. The second part of the study aims to establish whether replacing the inner part of the knee cap is beneficial for patients in reducing the likelihood of pain being caused. The third question concerns 'mobile bearings', and whether the introduction of these is beneficial to patients who undergo a knee replacement procedure. The final part of the study involves unicompartmental knee replacements, and aims to ascertain whether these are advantageous in certain situations.

Patients who join the study are asked to fill in questionnaires about their knee before their operation, three months afterwards, and then on a yearly basis for up to 10 years. Details of the operation are collected by the surgeon and a member of the research team visits participants before they leave hospital. No additional hospital visits or tests are required.

The applicant now wishes to use HES data to supplement the data already collected from the participants and it is the applicant's belief that a combination of their patient information leaflet and signed consent form demonstrate informed consent by all KAT participants.

The Group questioned whether this is an ongoing project and whether recruitment to the study is now closed. The Group raised concerns around the consent wording, which references the collection of "NHS information to do with … knee replacement". However, the applicant would receive more information than simply information about knee operations in their extract. Members were also of the opinion that as the applicant was sending follow-up questionnaires to participants, they should be able to approach patients with revised consent wording, which should contain the DAAG approved wording.

Outcome letter to be sent to applicant.

<u>181011-b – Gynaecological Cancer Research Centre, UCL Institute of Women's Health</u>

UKCTOCS is a Randomised control trial of Ovarian Cancer screening involving 202638 volunteers. 50% of participants receive 6 annual screens, 100% of participants receive 3.5 and 10 year health related questionnaires. The main outcome of the trial is to compare morbidity due to Ovarian Cancer between screened and non-screened arms.

The study finished recruiting its target of 200,000 post-menopausal women in 2005. Screening for ovarian cancer continues to the end of 2011 with a 3 year follow-up period to identify primary outcome diagnosis of Ovarian and tubal cancer.

The HES data has been used to identify participants who have been admitted for cancer-related treatment. Although the primary cancer of interest is ovarian and fallopian-tube, the study is also looking at Endometrial and Breast cancer.

As detailed above, the applicant now wishes to write to consultants who were responsible for the procedure identified in the HES data in order to obtain histology and surgery data in order to accurately determine disease diagnosis. The requested information will include histological diagnosis (e.g. stage and grade) and details of operation procedure and treatment.

The group approved this application.

Action: Approval letter to be sent to applicant.

<u>181011-c – Dr Foster Intelligence</u>

This application from Dr Foster Intelligence sought permission for the Dr Foster Unit at Imperial College London (DFU) to release a full HES extract of patient episode records including sensitive fields.

DFU currently provide DFI with a SUS feed which is in clear and includes the sensitive data items

	requested. Approval to provide this data was granted by PIAG Ref: 2-05(d)/2007 and is reviewed annually. This application seeks to gain approval from DAAG for the same sensitive fields to be provided from HES not SUS, and this feed would be supplied by DFU. The data is required by DFI to overright the current SUS historical data with the Fixed 'Gold Standard' HES data The group approved this application. **Action:** Approval letter to be sent to applicant.
081111-e	**NHS Central Register – MRIS Applications** <u>MR1244 – University of Southampton Clinical Trials Unit</u> Alcohol-related liver disease (ALD) accounts for the majority of alcohol-related deaths in the United Kingdom. Whilst many patients presenting with alcoholic liver disease will have cirrhosis, as many as 60% will have evidence of an alcohol-related hepatitis. Alcoholic hepatitis is the most florid manifestation of alcohol-related liver disease, but is potentially reversible. However, despite the increasing prevalence and the severity of this disease, there is no consistency in its management. Considerable controversy exists, especially regarding the use of corticosteroids. The primary objective of this trial is to determine whether prednisolone or pentoxifylline improve the 28 day mortality from severe alcoholic hepatitis. Data supplied by MRIS will be used for long-term follow-up of patients in the event that patients are lost to follow-up in the clinical centres. The customer was advised to amend the consent materials to cover cross border movements into Scotland and Scottish members as the initial forms drafted would not have been accepted. The specific consent form has now been amended and recommended wording used. **The group approved this application.** <u>MR1243 – The National Hospital for Neurology and Neurosurgery, London</u> This will be a prospective, multicentre, inception cohort study in 1000 patients with ischaemic stroke due to AF started on warfarin. Patients will have genetic testing and standardized MRI including GRE at baseline, with follow-up 6-monthly by telephone questionnaire (and clinical assessment or medical records surveillance after suspected events), and final clinical assessment at 2 years. We will compare the rate of symptomatic ICH between MB and MB-free patients and test for associations with plausible candidate genes. The follow- up questionnaires will be sent out for up to 4 years. Contact must be made with each patient on a 6 monthly basis and therefore up to date, accurate information about their status must be made available to the researchers prior to contacting the patient. Information about death and cause of death are vital for accurate follow up and analyses, and to ensure families are not approached after a relative's death. Initial consent materials were not particularly clear and also mentioned data leaving the researcher would have person ID info removed. Customer has now amended the consent materials to include the recommended words verbatim and removed the statement re person ID data being removed. Recruitment is yet to start. **The group approved this application.** **Notification to committee:** <u>MR1129- FPT</u> This application relates to MR1129 SCORAD feasibility study and is now running as a full phase trail. customer has requested keeping the two phases together as members of the feasibility study will no included in the full phase. There are no significant changes from the feasibility stage other than this being conducted as a full phase trial. MR129, MR168, MR187, MR250 and MR132 – these effectively all come under one new S251

	application but refer to 5 'historic' MRC cohorts. This application covers 5 'historical' study cohorts held by MRIS. The studies ceased notification aroun time of S60 with the intention of re commencing at some point in the future. The studies now have S support across all 5 studies ECC 5-04(g)/2011. ONS AR/MRP is in place.
081111-f	**Any other business:** DAAG Website - The group were happy with the new website and the dates for next years DAAG meetings will be posted on the website. Clare Sanderson will put forward a paper to ECC regarding consent wording, to advise that if the DAAG group receive any applications where the consent wording is in question, the group will refer them to ECC for further discussions to ensure everything is clear. Clare will also include in her paper a request for someone from ECC to join the group. Clare Sanderson will circulate her paper to ECC about consent to the group for comments. De-identification standard – A workshop took place with Phil Walker on 7th October 2011. Clare will keep the group updated with progress. HES Audit – Results of the HES Audit had revisited some issues. Clare will provide an update to the group at the next meeting, along with the action plan. It was agreed that, when arranging submission deadlines for 2012 DAAG meetings, the deadline for papers to be submitted to members prior to the meetings would be 10 days before the meeting takes place. The Chair informed the group that Dame Fiona Caldicott has been asked to carry out a review of consent and it was suggested that DAAG pull together some point to submit. The Chair thanked Patrick Coyle for his invaluable contribution to the Group in light of his term of office with ECC coming to an end, and for his agreement to continue to serve as a member on the Group. ECC are to be asked to nominate another of their members to join DAAG.
	Date of next meeting: 22nd November 2011