

Data Access Advisory Group

Minutes of meeting held 7 May 2014

Members: Alan Hassey (Acting Chair), Patrick Coyle, Dawn Foster, Sean Kirwan

In attendance: Susan Milner, Diane Pryce, Frances Hancox (Secretariat), Jackie Gallagher, Garry Coleman (agenda items 070514-c to -e only)

Apologies: None

070514-a	<p>Welcome</p> <p>The Acting Chair read a statement on behalf of Rob Shaw and Simon Gray, explaining the current approach to data approvals. It was noted that in the interim period, DAAG would make recommendations on whether or not to approve applications and these would be given to Rob Shaw for final approval and the issue of outcome letters.</p>
070514-b	<p>Minutes of the previous meeting</p> <p>The minutes of the 27 February meeting were agreed as an accurate record.</p>
070514-c	<p>Matters Arising</p> <p>(a) Overview of outstanding actions</p> <ul style="list-style-type: none">• <i>240413-c1: Diane Pryce and Clare Sanderson to discuss differences between the application process in Scotland and England, and consider meeting with NHS Scotland.</i> As future processes had not yet been confirmed, it was agreed that this action would be closed but that it would be raised as a DAAG agenda item in approximately July 2014, once further clarity was available.• <i>310713-c1: Dawn Foster to schedule a workshop to review the data sharing contract and invite other DAAG members to participate.</i> It was agreed that this would be covered as part of the wider review of data sharing processed. The action was closed, and it was agreed that this would be brought back to a later DAAG meeting as an agenda item once further updates were available.• <i>300114-c1: Mark Davies to ensure Alan Perkins and Kingsley Manning are aware of the CQC application (270613-d).</i> This action had been completed, but there was an additional outstanding action around determining whether CQC wished to meet with DAAG members to discuss this. It was since this application was discussed, CQC had made a new IG Toolkit submission and their scores had now improved; this meant that there were now no significant concerns. The action was therefore closed.• <i>300114-g1: Mark Davies to write to University of Sheffield (application 191113-d1) regarding re-contacting participants who had consented to participate in the study using the old consent form.</i> A letter had been sent to the applicant seeking further information.• <i>300114-g3: Dawn Foster to contact the ICO regarding consent obtained from individuals who subsequently lost mental capacity.</i>

A response had been received from the ICO stated that this was considered to be an ethical issue, and that if consent had been obtained at the beginning of the study then there was no requirement to continually seek to re-consent participants. However the ICO response suggested that if a study were based around a topic such as dementia where this might be a particular issue, then they would advocate asking participants when their original consent was sought how they would wish their data to be treated if they lost mental capacity.

- *270214-g1: Frances Hancox to update the DAAG Register of Approved Applications.*

The updated Register of Approved Applications had been published.

(b) Overview of outstanding applications

MR1337: Mortality outcome in the London COPD cohort

This application remained on hold due to organisational changes within the applicant organisation.

MR1328: The Birmingham Lung Improvement Studies BLISS

This application had been recommended for approval at the 27 February 2014 DAAG meeting, but as this was an application for new data it was suggested that it would be appropriate to discuss it with the relevant Information Asset Owner (IAO) and bring back through the updated DAAG process as soon as possible.

270214-a: The King's Fund (renewal)

This application had also been recommended for approval at the 27 February 2014 DAAG meeting, but it was thought to be on hold due to uncertainties around the current process in place. It was agreed that this would be discussed outside the meeting.

270214-b: The MIDSHIPS Trial

This application had been recommended for approval, and an outcome letter from Rob Shaw would be going out to the applicant.

270214-c: Unit of Health-Care Epidemiology, Oxford University

The Group had discussed this application at the 27 February 2014 meeting and suggested that the applicant should go back to the HRA Confidentiality Advisory Group (CAG) as the requested data appeared to be identifiable. It was confirmed that the data requested would be encrypted with one-way encryption, and that CAG had been content that it would not require Section 251 support. It was agreed that the draft outcome letter would be sent to the Acting Chair for review.

171213-d1: UK Biobank

This applicant had previously applied to DAAG for additional data; this was discussed at the 17 December 2013 DAAG meeting and the Group had written to the applicant to emphasise the importance of ensuring fair processing of data under the Data Protection Act, particularly by making information available to participants about how their data would be used. In addition the Group had requested sight of the information materials that would be sent to participants. The applicant had subsequently responded and their response was circulated around the Group. However it was noted that due to the updated DAAG process, this application might need to be brought back to the Group once it had been discussed with the relevant IAO.

	<p>At this point Garry Coleman joined the meeting.</p> <p>(c) Decisions out of committee</p> <p>No out of committee decisions had been made since the previous DAAG meeting.</p>
070514-d	<p>DAAG Terms of Reference</p> <p>A draft version of the DAAG Terms of Reference had been circulated which included a number of draft updates around the current role of DAAG, and the Group were asked for their comments. It was agreed that the changes were appropriate, and the Group agreed to adopt the updated Terms of Reference. One query was raised regarding a reference to the National Information Governance Board (NIGB), which was no longer felt to be relevant as NIGB had ceased to exist, and it was agreed that this would be updated.</p> <p>There was also a discussion around the membership of DAAG, and it was agreed that it would be appropriate and useful if an additional independent member could be added to the group in order to increase its independence. It was noted that the Acting Chair had initiated some discussions around this with the Chair of HRA CAG, and the Group agreed that he should seek agreement from within the HSCIC to add an additional independent member.</p> <p>It was confirmed that in its current role DAAG should be considered advisory rather than decision making, and that recommendations to approve or not approve applications would be made to the HSCIC Board. Outcome letters would then be issued to applicants by Rob Shaw, HSCIC Director of Operations and Technical Services, in his role as Senior Information Responsible Officer.</p> <p>Action: Sean Kirwan to suggest updated DAAG Terms of Reference wording to replace current reference to NIGB.</p> <p>Action: Frances Hancox to publish updated DAAG Terms of Reference.</p>
070514-e	<p>HES Applications</p> <p><u>070514-e1: The HALT-IT Trial, London School of Hygiene and Tropical Medicine</u></p> <p>For this application, the applicant would provide NHS numbers, dates of birth, postcode and patient initials in order for the HSCIC to create a linked HES extract. Some concerns had been raised with the applicant that the consent materials used did not adequately described the intended data sharing and processing, and as recruitment would continue for a number of years it had been suggested that the consent materials should be updated for all future recruitment. The applicant had provided a response, which was included with the application papers provided.</p> <p>The Group agreed that the applicant's consent materials should be amended to include the recommended wording about data sharing and processing, and that the updated consent materials should be used for all future recruitment. A query was raised regarding whether this would mean the applicant would need to go back to their Research Ethics Committee (REC) to gain approval again, and it was stated that this would depend on the individual REC.</p> <p>It was also noted that as the application was for a worldwide study, there would be the potential for data to be shared outside the UK although the applicant had confirmed that this would not include personal identifiable data. The Group were informed that the applicant would need to seek further approvals to share data outside the UK.</p> <p>Outcome: The Group were unable to recommend for approval. Further information</p>

	<p>requested from applicant.</p> <p><u>070514-e2: Choosing Healthcare Options in Chronic Care Emergencies (CHOICE) quantitative study, Manchester Mental Health & Social Care Trust</u></p> <p>This applicant had approached the HSCIC for HES data for a small number of the participants in their study, as the data previously obtained from their general practice records had been incomplete. The participants had previously been contacted by their GP to ask them to consent to participate in the study, and there were some concerns raised around using this consent as the basis for the proposed data sharing as the GP letter had indicated that the study would be completed in 2011, and gave no indication that HES data would be used.</p> <p>It was noted that the number of participants for whom data had been requested was relatively small, and the Group agreed that if the applicant were still in contact then it would be practical for the applicant to inform each applicable participant about the proposed data extraction and ask them for their consent to this. The Group agreed that the applicant should ask the relevant participants to re-consent to the proposed use of their data.</p> <p>Outcome: The Group were unable to recommend for approval. Further information requested from applicant.</p> <p><u>070514-e3: Royal College of Surgeons (Morecambe Bay Investigation)</u></p> <p>It was explained that the HSCIC had an existing agreement in place with the applicant to allow them to access HES data, and that the applicant had S251 support for this. The applicant had now been asked by the Department of Health to carry out an investigation into a series of death of mothers and newborn babies with Morecambe Bay NHS Foundation Trust, and this would require an amendment to the existing agreement. It was noted that the Section 251 approval from HRA CAG was now out of date and that CAG were looking at extending this to cover the requested work.</p> <p>The Group agreed that this was an important piece of work, and there were no concerns around the application. It was agreed that the application should be recommended for approval, once the CAG application to extend the Section 251 approval had been completed.</p> <p>Outcome: Recommendation to approve</p>
<p>070514-f</p>	<p>Data linkage and extract service (MRIS) applications</p> <p><u>MR1332: The Cleft Collective Cohort Studies</u></p> <p>The applicant had requested biannual reports of patient identifiable data from MIDAS for the participants who had consented to take part in the study. This data would be used to study the impact of being born with a cleft palate.</p> <p>A number of different consent forms had been produced to be used by participants within different age groups. The Group were informed that all three consent forms included the recommended consent wording, and the patient information literature also included a statement that described the data sharing process. The Group agreed that they were content with the consent materials provided, and that the proposed study seemed like an appropriate use of data.</p> <p>Outcome: Recommendation to approve</p>

<p>070514-g</p>	<p>DAAG application format</p> <p>It was noted that the DAAG application summary template had been updated to incorporate a checklist and make the documents easier to read, and the DAAG members were told that any feedback on the updated format would be welcome.</p> <p>An application tracking database had also been created, which would be used to track which applications were due to be discussed at each DAAG meeting and how applications had progressed following their consideration by DAAG. It was agreed that this would be circulated along with the papers for the next DAAG meeting.</p>
<p>070514-h</p>	<p>Any other business:</p> <p>It was noted that a Freedom of Information (FOI) request had been received regarding the request from the Cabinet Office (OC/HES/030) which had been considered out of committee in June 2013 and retrospectively recorded in the minutes of the 30 January 2014 DAAG meeting. A response to this FOI request was being drafted.</p>

Summary of Open Actions

Reference	Action	Owner
070514-d1	Sean Kirwan to suggest updated DAAG Terms of Reference wording to replace current reference to NIGB.	Sean Kirwan
070514-d2	Frances Hancox to publish updated DAAG Terms of Reference.	Frances Hancox