NHS
Health Research Authority

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

January 2015

Present:

Name	Capacity	Items
Dr Tony Calland MBE (Vice Chair)		1a, 1b, 1c
Mr Anthony Kane	Lay	1a
Professor Jennifer Kurinczuk		1a, 1c
Professor Barry Evans		1b
Dr Miranda Wolpert		1a, 1b, 1c

Also in attendance:

Name	Position (or reason for attending)
Mr John Robinson	Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 14/CAG/1033 Maternal Serum PAPPA levels and pregnancy outcomes

This application from Birmingham Women's Hospital NHS Foundation Trust set out the purpose of time limited access to perform data linkages of hospital records prior to the anonymisation of the study dataset.

The study will involve a systematic review to assess the predictive accuracy of first trimester serum PAPPA (alone or in combination with other markers for example first trimester uterine artery Doppler) for adverse pregnancy outcomes measured in terms of pregnancy loss, perinatal mortality, preterm birth, intrauterine death (IUD) and small for gestational age (SGA) . The study also seeks to assess the predictive accuracy of first trimester serum PAPPA alone or in combination with other biometric indicators for adverse pregnancy outcome in the population at Birmingham Women's Hospital NHS Foundation Trust (BWNFT).

The data collected in this study from the computer systems at Birmingham Women's Hospital NHS Foundation Trust will be anonymised and a unique identifier will be utilised in place of personal identifiers.

Class 4 and 6 support is being requested to allow access for authorised users to link patient identifiable information obtained for more than one source.

Confidential patient information requested

Access is requested to NHS number, hospital number, date of birth, district level postcode (for deprivation analysis) and ethnicity.

Confidentiality Advisory Group advice

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

Although members appreciated that seeking consent from 15,000 women prevented consent from being a practical alternative for this application, it was unclear why contacting patients retrospectively would necessarily result in causing upset to those women. Members agreed that consent would not be possible due to the number of women who would be involved in this study.

It was noted that data collected for the study would be anonymised and that a unique identifier will be used in place of personal identifiers, therefore researchers should only have temporarily access to confidential patient information.

Fair processing

It is a requirement of the Regulations that an application cannot be inconsistent with the principles of the Data Protection Act 1998 (DPA). The first principle of the DPA requires that reasonable efforts are made to inform data subjects of the use of their data.

It was noted that a leaflet is made available to all patients by the Trust that advises that research is taking place within the organisation and provides an opportunity for patients to dissent from this. Members stated that this was not adequate as a tool to advise patients how their data would be used within this research project and it was suggested that the applicant may wish to consider the provision of posters in key community health settings to enhance awareness of this project and provide the opportunity for dissent.

Further information and suggestions in relation to the fair processing of data can be found on the Information Commissioner's Office website – http://ico.org.uk/for_organisations/data_protection/the_guide/principle_1#fair-processing and within the Privacy Notices Code of Practice - http://ico.org.uk/for_organisations/data_protection/topic_guides/privacy_notices.

CAG advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in research of this nature being conducted, and therefore advised recommending provisional support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. The applicant should seek advice from the Information Commissioner's Office in relation to the fair processing of data specifically for this application and consider the suggestion of the CAG in relation to providing information in key community health settings.
2. Favourable opinion from a Research Ethics Committee.
3. Confirmation of suitable security arrangements via Information Governance Toolkit (IGT) submission

b) 14/CAG/1034 Collaborative European Neuro-Trauma Effectiveness Research in TBI: a prospective longitudinal observational study

This application from Cambridge University Hospitals NHS Foundation Trust set out the purpose of accessing confidential patient information to produce an anonymised data registry.

CENTER-TBI is a European Union funded observational study that aims to improve the care of patients suffering from Traumatic Brain Injury (TBI). This observational study has been created due to the substantial number of people who experience TBI. TBI is also associated with high levels of death and disability and causes great personal suffering to victims and relatives. The study seeks to explore current treatment methods as existing evidence is now outdated. It has also been identified that treatments are not standardised and vary according to where patients are treated.

The Applicant is requesting support under Section 251 of the NHS Act 2006 to collect basic clinical and treatment information without consent so that evidence can be generated about the most effective treatments.

Class 1, 5 and 6 support is being requested to allow access of an authorised user to support the process of extracting and anonymising the information and for auditing, monitoring and analysing patient care and treatment.

<u>Confidential patient information requested</u>

Access is requested to collect age (in years), date of injury, sex, American Society of Anaesthesiologists Physical Status Score, anticoagulant therapy, injury severity score, type of injury, location of incident (home, street, public place, work, sports field), date and date of CT, CT results, pre-hospital care details, date and time of arrival to hospital, admission level (ward, ICU), GCS score, pupil response, blood pressure, oxygen saturation, treatment procedures in study centre, discharge status (mortality), discharge destination, principle cause of death (if appropriate), duration of survival.

Confidentiality Advisory Group advice

Members reviewed the registry aspect of the application for which support was being requested.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

Members noted that consent would not be feasible due to the volume of patients, local capabilities and the potential for non-response.

It was noted that only anonymised routine information would be collected for use in the registry and that researchers would access patient notes themselves in some instances where a member of the patient's care team were unable to perform the anonymised extraction.

Justification of identifiers

It was noted that researchers would only have access to identifiable data whilst they were reviewing patient records and that no identifiable data would be extracted or retained.

Additional points

Members were not clear of the estimated number of patients that would be included in the registry from each of the sites.

Members noted that the Confidentiality Advisory Group had been referred to as the Confidentiality Advisory Board in the poster that was submitted as part of this application. The Applicant was requested to correct the poster by referencing the "Confidentiality Advisory Group".

CAG advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in research of this nature being conducted, and therefore advised recommending provisional support to the Health Research Authority, subject to compliance with the specific and standard conditions of support and further clarifications as set out below.

Specific conditions of support

1. The poster to be corrected to refer to the "Confidentiality Advisory Group" rather than the Confidentiality Advisory Board.
2. Favourable opinion from a Research Ethics Committee.

3. Confirmation of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Request for clarification

1. Confirmation as to the estimated number of patients that may be included in the registry from each of the UK sites.

c) 14/CAG/1036 A new combined radiological and clinical classification for pulmonary embolism using computed tomography pulmonary angiography

This application from the University of Keele set out the purpose of reviewing radiology images, report and patient notes of patients who have a massive pulmonary embolism. Data will be collected and analysed in an anonymised format to establish a new classification based upon the radiology images and other relevant patient investigations. The new classification will be developed for clinical practice to aid the direction of patient treatment and long term follow up.

The Applicant notes that presently there are many current systems for assessing pulmonary embolisms found on CT pulmonary angiography alone, and only a few assessments that consider a patients clinical status, however details such as heart rate and blood pressure can inform medical teams about a patient's heart and circulatory reserve. The development of a tool that incorporates clinical status, the Applicant believes would alleviate some of the difficulties with the existing technical scoring systems and provide a more holistic approach.

A recommendation for class 1, 5 and 6 support was requested to cover access to allow access for an authorised user to process of extracting and anonymising the information, and for auditing, monitoring and analysing patient care and treatment.

Confidential patient information requested

Access was requested to hospital number, gender, age, co-morbidities, clinical presentation and imaging findings.

Confidentiality Advisory Group advice

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

The Applicant advised in their response to the queries raised within the CAT Advice Form on 21 November 2014 that consent was not feasible due to some of the patients now being deceased and because approaching relatives in such instances could be harmful and distressing.

It was noted that no identifiable data would be retained by the researchers as this application was to enable the researchers to access patient data to extract anonymised data.

Justification of identifiers

The temporary access of patient identifiable data to perform the anonymised extraction for this study was supported by Members. A reasonable alternative method of producing the desired data without identifiable data also being accessed could not be identified by Members.

CAG advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in research of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Received 1 December 2014.**
2. Confirmation of suitable security arrangements via Information Governance Toolkit (IGT) submission.

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Present:

Name	Capacity	Items
Dr Patrick Coyle (Vice Chair)		1a

Also in attendance:

Name	Position (or reason for attending)
Mr John Robinson	Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW AMENDMENTS – RESEARCH

a) ECC 1-04(b)/2010 Evaluating the age extension of the NHS Breast Screening programme in England

This application from the University of Oxford built upon a pilot study that aimed to investigate the feasibility and acceptability of randomising the phasing-in of the age extension of the NHS Breast Screening Programme in England. This application proposed investigating the randomising of the phase-in of the age extension through collecting information on breast cancer and mortality over the following 10 years. A recommendation for class 1, 2, 4, 5 and 6 support was requested to permit data from the National Breast Screening Services to be downloaded for all participants randomised in and out of the study so that they could be flagged at the NHS Central Register for follow-up in relation to cancer incidence and mortality. Additionally, support under section 251 was requested so that clinical screening follow up date could be transferred to the researcher team outside of the direct healthcare team for those participants randomised into the study. It was noted that those participants randomised out would not be made aware that they were part of the study.

Amendment request

The Applicant advised there had been changes to the trial documentation however this respected the request of the Research Ethics Committee and did not change the trial design or methodology.

In addition to these changes, it was noted that support was requested to perform further data linkages and collect additional data items from NHS screening records,

cancer outcomes datasets and Hospital Episode Statistics to contribute to the assessment of risks associated with screening and to provide comprehensive information on characteristics of incident cancers and their treatment.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Vice Chair who acknowledged that these further linkages would increase the value of the study. It was noted that the additional linkages would not require any additional identifiers to be retained and identifiers would continue to be removed once the linkages have been performed.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **Confirmed 20 November 2014.**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 5 October 2014.**

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Present:

Name	Position (or reason for attending)
Ms Claire Edgeworth	Deputy Confidentiality Advice Manager, HRA

1. NEW PRECEDENT SET REVIEW AMENDMENTS – RESEARCH

a) CAG 1-06(PR7)/2013 Secondary Prevention of Burns and Scalds in Children

This application from the University of Cardiff described a study to evaluate a risk assessment tool designed to assess childhood burns and direct to appropriate care. The application was for the pilot study only.

The application followed on from a previous PIAG approval which was obtained in order to establish the risk assessment tool, PIAG 4-05(i)/2008 Thermal injuries in children - Version 1.

Confidential patient information requested

The application requested approval to access data in relation to patients under the age of 16 who have presented with scalds and non-scald burns at emergency departments over a 12 month period over 3 NHS Trusts. Clinical staff would complete a data collection form on behalf of the research team who would then use identifiable details to request further information from other services such as health visitors, social workers, school nurses and children centres.

Name, hospital or NHS number and date of birth would be collected in order to carry out linkages. Identifiable data items would be removed from the database once linkages were complete.

Amendment request

This is a geographical and time extension to include North Manchester General Hospital (part of Pennine Acute Hospitals Trust)

Confidentiality Advice Team advice

It was queried why it was deemed necessary to collect data on additional sites and why the data collection period needed to be extended, whether it was still phase 1 of the study or had it been extended to Phase 2.

The applicant's response confirmed that:

1. Data was still being collected under phase one approvals.
2. It was necessary to extend data collecting for this phase to establish a baseline for Manchester.

Health Research Authority recommendation

Following advice from the Confidentiality Advice Team, the Health Research Authority agreed to recommend support to the Secretary of State for Health, in line with the conditions and clarifications highlighted by the Confidentiality Advice Team.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission.
2. Confirmation of a favourable opinion from a Research Ethics Committee.