Minutes of the meeting of the Precedent Set Sub Committees of the Confidentiality Advisory Group

June 2015

Reviewers:

Name	Capacity	Items
Dr Tony Calland	Chair	1
Professor Barry Evans		1
Dr Miranda Wolpert		1

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) Integrate - 15/CAG/0131

Purpose of application

This application from the University of Liverpool set out the purpose of a prospective study to develop an enhanced surveillance and management system. The study will identify and clinically investigate individuals with the symptoms of gastrointestinal illness, from oral notification of symptoms to laboratory investigation of samples. The integrated real-time, surveillance/diagnosis/investigation system was centred on the patient to detect community outbreaks sooner, enable Health Protection professionals and Environmental Health Officers to intervene quickly and to lessen short and long-term harm. To develop the integrate system, part one of the research was to conduct a retrospective study to identify high risk or high incidence through the analysis of public health surveillance data collected through a number of sources, including but not limited to NHS 111 and Public Health England. Part two of the study included contacting patients to seek consent to participate within the laboratory based studies.

A recommendation for class 2, 4 and 6 support was requested to cover access to an authorised user to obtain and use information about the past or present geographical location and also to link patient identifiable information obtained from one or more source.

Confidential patient information requested

Access was requested to name, NHS number, date of birth and postcode.

Confidentiality Advisory Group advice

Public interest

Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006. Members agreed that the activity carried out would likely to provide a public interest as Gastroenteritis is common and can lead to more serious complications within patients.

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 agreed that seeking consent for part one of the study would not be feasible due to the retrospective nature of the cohort in which it would be difficult to obtain consent. For part two of the study, Members agreed that the purpose of the application was to acquire contact details in order to obtain consent from the patients.

Justification of identifiers

Members highlighted that the specified identifiers are justified for the purpose of obtaining updated contact details to seek consent from patients and to use postcode to map recent patterns of incidence.

Members advised that once the activity of tracing and obtaining contact details had been completed, the identifiers should be removed for patients who had not responded or provided consent. Members advised that identifiers acquired from updated consent from patients, should be retained for future follow-up studies. Members also advised that the identifiers should be removed from retrospective study data and to pseudonymised/anonymise the data as soon as reasonably practicable.

Additional points

Members noted that the second line, second paragraph within the patient leaflet, there was a word missing. It stated ‘time work’ instead of ‘time off work’ and members noted that the leaflet should be amended.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects 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. Amend ‘time work’ to ‘time off work’ within the patient information leaflet.
2. Favourable opinion from a Research Ethics Committee. Confirmed 19th March 2015

3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. Confirmed 25th March 2015.

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

Amendments June 2015

Reviewers:

Name	Capacity	Items
Dr Robert Carr		1a
Professor Barry Evans		1a, 2a
Dr Patrick Coyle	Chair	1a
Mr Marc Taylor		2a
Dr Mark Taylor	Chair	2a, 1b
Mr Anthony Kane		1b
Ms Clare Sanderson		1b

1. AMENDMENT – NON-RESEARCH

a) National Joint Registry PIAG 2-05(j)/2006

Context

Purpose of application

This audit application from the Healthcare Quality Improvement Partnership (HQIP) sought support for the collection of data on hip, knee, ankle, elbow, and shoulder replacement procedures carried out in England, Wales, and Northern Ireland, in both the NHS and independent healthcare sectors. The underlying aims for which this data was collected were to:

- Monitor in real time the outcomes achieved by brand of prosthesis, hospital and surgeon, and highlight where these fall below an expected performance in order to allow prompt investigation and to support follow-up action.
- Inform patients, clinicians, providers and commissioners of healthcare, regulators, and implant suppliers of the outcomes achieved in joint replacement surgery.
- Evidence variations in outcome achieved across surgical practice in order to inform best practice.
- Enhance patient awareness of joint replacement outcomes to better inform patient choice and patients' quality of experience through engagement with patients and patient organisations.

- Support evidence-based purchasing of joint replacement implants for healthcare providers to support quality and cost effectiveness.
- Support suppliers in the routine post market surveillance of implants and provide information to clinicians, patients, hospital management and the regulatory authorities.

A recommendation for class 1, 4, 5 and 6 support was requested to cover continued access to patient data where consent had not been recorded on the data collection form, and continued permission to link National Joint Registry data to Hospital Episode Statistics (HES), Patient Episode Database Wales (PEDW) and Patient Reported Outcome Measures (PROMs) datasets. It was noted that the National Joint Registry had been a mandatory data collection for the NHS since April 2011.

Confidential patient information requested

Access was requested to name, date of birth, address, postcode, NHS number and gender.

Amendment request

The amendment request confirmed that, in line with the original application for support, the continued need for the NJR to undertake outcomes analyses for joint replacement surgery, including risk adjusted mortality rates. In order to undertake these analyses, it was necessary to know a patient's date of death and the causes of death. As linkage to these ONS data items was not specifically mentioned within the original application the amendment sought to clarify the support provided.

Confidentiality Advisory Group advice

This was forwarded to a sub-group of members who noted that the omission of reference to ONS data within the original application appeared to be an oversight and that the linkage to this data would be required in order to meet the aims specified within the original application.

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 Secretary of State for Health.

b) Inflammatory Bowel Disease Registry - CAG 6-07(d)/2013

Context

The original audit application from the British Society of Gastroenterology set out the purpose of establishing a national IBD Registry which would feed into national service development planning and fulfil national audit, IBD standards and quality improvement benchmarks. The application also detailed using the registry to allow patients to be identified for research purposes and for the Health and Social Care Information Centre (HSCIC) to write to patients on behalf of the applicant. A recommendation for class 4, 5 and 6 support was requested in order to access data, including NHS number, date of birth and postcode in relation to all patients in the UK who had been diagnosed with IBD. Data

sources included HES, ONS, Bowel Cancer audit, cancer registries, IBD Registry patient management system and data collected via a web portal system. Data would be collected by the HSCIC and only pseudonymised data would be disclosed to the British Society of Gastroenterology for analysis purposes.

Amendment Request

The applicant submitted the following amendments to the original application:

1. The applicant proposed interim processing arrangements whilst the applicant undertake and publish a satisfactory Information Governance Toolkit in order to ensure sufficient compliance with up to date security measures. The applicant proposed that pseudonymised data from the Health and Social Care Information Centre (HSCIC) would flow to Chameleon Information Management Services Ltd (CIMS) for the purpose of checking and adjusting coding anomalies before exporting the data files in the format required by the University of Liverpool. The applicant also proposed that the University of Liverpool will undertake analysis of the demographic and clinical data, combine this with the linked HES data, and produce reports of aggregated data ensuring that appropriate standards of anonymisation have been observed. Individual feedback reports will be provided to each of the hospitals that have submitted data to the Registry and a 'national' report will be produced. The aggregated data will be also be provided to the Registry team to be used for publications and conference presentations. The applicant noted that once the British Society of Gastroenterology (BSG) completes and receive confirmation from the Health and Social Care Information Centre (HSCIC) that the BSG Information Governance Toolkit is of satisfactory compliance, the BSG will commence the direct processing of the data.

2. The applicant submitted a request to revise the original s251 support outcome letter to include gender, consultant code [HES] and GP code [HES] to the list identifiers required.

3. The applicant requested an amendment to the original application to include ethnicity within the list of identifiers.

4. The applicant requested an amendment to the original application to include access, the linking of demographic data and clinical data to the Patient Episode Database for Wales (PEDW) and the resultant pseudonymisation of the data.

5. The applicant requested an amendment to the original application to include the University of Liverpool as a data processor in order to reflect the decision to contract out the analysis and reporting of registry data.

6. The applicant submitted a request to reschedule the project from the previous start date of May 2014 to January 2015 in order to distribute consent materials to clinical teams.

Confidentiality Advisory Group Advice

The amendment request was submitted to the Chair for review and due to the substantial nature of the amendments, the Chair deferred the application to the sub-committee.

Interim Processing Arrangements

Members agreed that the interim processing arrangements were necessary in order to ensure that there were sufficient security mechanisms in place to process the pseudonymised data which flow from the HSCIC to CIMS and the University of Liverpool. Members noted that once BSG completes and receive confirmation from the HSCIC that the Information Governance Toolkit is of satisfactory compliance, BSG will commence the direct processing of the data. Members advised contacting the Health Research Authority to confirm when BSG will commence direct processing.

Identifiers

Members noted that gender, consultant code [HES] and GP code [HES] were included within the original application and noted that it was reasonable to include the identifiers for the purposes for which they are required for. Members noted that the applicant do not currently plan to publish data by consultant or GP code, however, advised that any data when published would need to be anonymised and if not properly agreed, could lay the applicant open to challenge.

Members agreed that the applicant provided sufficient reasons for the requirement to include ethnicity within the list of identifiers.

Access, linking and pseudonymisation of Patient Episode Database for Wales (PEDW) Data

Members noted that the original application stated that the registry would include 'all patients in the UK' and agreed that access to PEDW data was a reasonable addition to the datasets in order to fulfil the application's purpose. However, the applicant noted within the amendment request form that the IBD Registry had not formally applied for access to PEDW and was in discussion with the NHS Wales Health Policy Team. The policy decision had been postponed until the outcome IBD audit NCAPCOP and the data security arrangements need to be agreed. Therefore, the applicant is advised to submit an amendment request once the security arrangements have been confirmed.

Data Processor

Members agreed that in order to carry out the processing on an interim basis, it was necessary for the original application to be amended to include University of Liverpool as a data processor. Members advised that all data processors involved within the interim arrangements should have completed Information Governance Toolkits and also received confirmation from the HSCIC that each Information Governance Toolkit is of satisfactory compliance prior to the commencement of processing.

Project Timescales

Members noted that the projected timeframe had lapsed and rendered the original period as inadequate. Members agreed the need to reschedule the start date from May 2014 to January 2015.

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 Secretary of State for Health.

Specific conditions of support

1. Processing of PEDW data is not included within this s251 support. Applicant is to submit a further amendment to CAG once PEDW security arrangements have been agreed.
2. Provide confirmation to CAG once BSG take over the direct processing of data. This would include providing confirmation from the HSCIC that BSG Information Governance Toolkit is of satisfactory compliance.
3. Confirmation of suitable security arrangements via IG Toolkit submission of Chameleon Information Management Services Ltd and University of Liverpool.

2. AMENDMENTS – RESEARCH

a) Whitehall II Study (Stress and Health Study)- CR2/2014

Context

Purpose of application

This application from University College London set out the purpose of a study to explore the relationship between socio-economic status and cardiovascular disease by examining the inter-relationships between contextual, biological, psychosocial and behavioural factors. Measures included blood pressure, blood sugar, blood lipid levels, height, weight, cardiovascular tests, walking speed, lung function, questions about diet, and five tests of mental functioning.

A recommendation for class support was requested to cover access to mortality data from the NHS Central Register, maintained by the Health and Social Care Information Centre (HSCIC). A cohort of 10,308 patients was flagged at the HSCIC.

This study had previously accessed data under the NHS Central Register (ECC 2-04(c)/2010) application.

Amendment request

The amendment request detailed access to HES data in order to estimate the contribution of midlife inflammatory, vascular, and metabolic factors to chronic disease, depression, cognitive impairment and functional health in later life, assess whether the adoption of healthy lifestyle even at older ages modifies functional trajectories, and also develop multi-factorial predictive algorithms, like those developed for cardiovascular diseases, to facilitate early identification of adverse ageing outcomes.

Confidentiality Advisory Group advice

The amendment request was forwarded to a sub-committee of members who requested confirmation that the data linkages would be undertaken in line with the original methodology specified within the application form. The applicant confirmed this. Members agreed that the request for HES data had been justified and that a practicable alternative could not be pursued in line with the original application.

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.

The following applications were referred to the CAG June full meeting from the June Precedent Set meetings:

- Simon Broome Familial Hypercholesterolaemia Register (MR180)
- Preceding Paraneoplastic Encephalitis in Ovarian Cancer [15/CAG/0140]

Chair's Action Report

June 2015

Officer:

Name	Capacity	Items
Dr Mark Taylor	Chair	1a
Dr Patrick Coyle	Chair	1b

1 – AMENDMENTS – RESEARCH

a) Building Blocks 2-6: parenting support to reduce maltreatment - CAG 10-08(b)/2014

Context

This application from Cardiff University set out the purpose of following up a cohort of 1562 women and children until the child reaches age of 6 in order to assess whether Family Nurse Partnership (FNP) reduces maltreatment of children.

A recommendation for class 4 and 6 support was requested in order to carry out linkage of Hospital Episode Statistics data to assess BB 0- 2 data which includes FNP data. Cardiff University would provide demographic data only to the Health and Social Care Information Centre (HSCIC) who would use this data to select relevant clinical records. Clinical data including the unique ID would be passed to Health Information Research Centre (HIRU) and linked using Secure Anonymised Information Linkage (SAIL). Cardiff University will provide the BB trial data to HIRU with the same unique ID. The linked dataset will be stored at HIRU.

Follow up data would be extracted at the child's 4th and 6th birthday.

Confidential patient information requested

Name, NHS number, GP registration and postcode would be provided in order to carry out linkages.

Amendment request

The amendment requested support to allow tracing at the HSCIC for those women who withdrew from the trial so that they could be sent further information in relation to follow up and allow data collection in line with the original approval.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who sought assurance that removal of consent to use any of their data was an explicit option that was offered to all patients who withdrew from the study. The applicant confirmed in an email dated 15 April 2015 that the withdrawal standard operating procedures specified that the research "must also ask the participant if data already collected from them can still be used", therefore this requirement was met. Those patients who had indicated that no further information should be used would not be included in the follow up. It was noted that the collection of follow up data in relation to these patients had been specified within the original application.

Confidentiality Advisory Group advice 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.

b) UK Surveillance of Primary Congenital Hypothyroidism in Children - ECC 3-04(k)/2011

Purpose of application

This research application from University College London set out the purpose to determine the incidence in the UK of confirmed diagnoses of primary Congenital Hypothyroidism (CHT) in children up to and including age 5 years, and to report the distribution by age, sex and ethnic group. It was noted that this application followed a very similar methodology to the British Paediatric Surveillance Unit (BPSU) 'orange card' reporting method. However, the difference with this application was that identifiable data would be retained for the purposes of long term monitoring of outcomes via Hospital Episodes Statistics (HES) and the Office for National Statistics (ONS). A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to these datasets.

Confidential patient information requested

Access was requested to NHS number, Hospital ID number, date of birth, date of death, postcode and sex.

Amendment request

The applicant submitted an amendment request to:

- Collect a third year of follow-up data on children notified to the study – this would provide a standard of outcome that had not previously been possible in observational studies of this condition.

- Migrate data from a secure data facility (epiLab-SS) external to UCL as this would cease to be supported by local information systems staff and responsibility transferred to UCL information systems staff during the next year. Data would be migrated to an equally secure internal UCL data facility that would be fully supported by UCL information systems staff for the long-term future.

The applicant confirmed the amendment would not affect the total duration of storage and use of identifiers as outlined in the original application.

Confidentiality Advisory Group advice

The Chair agreed that the amendment was justified both for the extra year and the change of venue for the secure storage of the data. It was noted that the condition required long term follow up. The Chair therefore agreed to recommend support for the application.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, it was 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.
2. Confirmation of a favourable opinion from a Research Ethics Committee.